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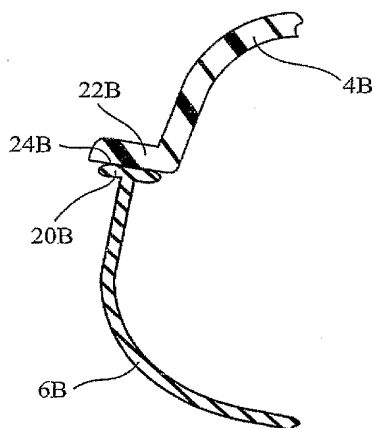
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(54) Title: RESPIRATORY MASK AND METHOD FOR MANUFACTURING A RESPIRATORY MASK



(57) Abstract: A respiratory mask, a mould for a respiratory mask, as well as to a method for producing a respiratory mask are disclosed, in which manufacturability and usability of respiratory masks are improved. A respiratory mask is disclosed for administering a breathable gas to a patient, the respiratory mask comprising a first component 6A formed from a flexible material and a second component 4A formed from a material that is more rigid than the flexible material, wherein the first component is formed onto the second component by an overmoulding process.

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TITLE OF THE INVENTION

RESPIRATORY MASK AND METHOD FOR MANUFACTURING A
RESPIRATORY MASK

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims the benefit of German Patent Application Nos. 10 2005 033 648.5 and 10 2005 033 650.7, each filed July 19, 2005 and incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

1.0 Technical Field

[0002] The invention relates to respiratory masks and manufacturing processes for respiratory masks. In particular, the invention relates to overmoulding portions of respiratory masks.

[0003] It should be noted that the phrase “respiratory mask” in this specification includes any type of patient interface, including full face masks, nasal masks, and nasal prong masks etc.

2.0 Introduction to Respiratory Masks

[0004] Respiratory masks are used for administering a breathable gas, such as ambient air, at a pressure that is, at least sometimes, above the ambient pressure. This is known as Positive Airway Pressure (PAP) therapy, such as Continuous Positive Airway Pressure (CPAP) or Variable Positive Airway Pressure (VPAP) therapy, and may be used for treating Sleep Disordered Breathing (SDB) or other medical conditions.

[0005] International Patent Application PCT/EP02/11798, filed by *Medizintechnik fur Arzt und Patient (MAP)*, now *ResMed Germany*, discloses a respiratory mask for administering a breathable gas to a user. This respiratory mask makes it possible, when worn by a user, to seal off an interior volume of the respiratory

mask from the environment. Such respiratory masks are used particularly in conjunction with medical or therapeutic administration of breathable gases (and additions thereto, such as drug vapours), as well as in the industrial field, for instance in the field of gas masks and breathing equipment. Typically, the interior volume is sealed using a sealing cushion or lip structure that is inwardly curved and extends around an opening in the mask and seals against the user's face. Sealing cushions are generally made from an elastically deformable material, such as silicone and seal by compression against the user's face. The level of sealing achieved generally increases with the contact pressure of the sealing cushion against the face.

2.1 Manual Labour

[0006] It is known amongst skilled persons that conventional mask systems are difficult to assemble. Consequently, assembly of components requires significant labour time, particularly while assemblers are learning. Further labour is required to check the correct assembly of mask components. Manual labour increases the cost of goods and subsequently may decrease the profitability of respiratory mask manufacturers and/or make masks more expensive for patients.

[0007] Automation of the manufacturing assembly process by using robotics, for example, is difficult due to the often complex manipulations required to assemble mask components. It is also known that flexible components, as are common in masks and mask systems, are exceedingly difficult to handle robotically. For automation to be achieved a very high level of robotic dexterity would be required and the expense of designing, manufacturing and configuring such robotics has generally been considered prohibitive.

2.2 Moulding

[0008] In general terms, the greater the number of components a mask includes, the more expensive it is to manufacture because more component moulds are required.

2.3 Assembly by Patients

[0009] Assembly and disassembly of mask components by patients can be difficult (e.g. after washing the mask prior to use). This problem is often exacerbated by the often relatively low dexterity of patient's suffering from sleep disordered breathing (e.g. because of age, weight or arthritis). Generally, therefore, the more components a mask has, the more difficult it is for patients to assemble. Furthermore, the higher the number of mask components, the greater the risk of those components getting lost and the greater the risk of mis-assembly.

2.4 Biological Contamination

[0010] Another problem with masks assembled from components that can be separated by a user is the build-up of biological contaminants in the crevices between the components, even when the mask is being regularly washed.

2.5 Mask Comfort

[0011] One ongoing problem encountered in mask design is the difficulty associated with creating a comfortable mask. Ordinary silicone membrane sealing technology can feel unpleasant and sometimes lead to pressure sores when the mask is tightened too much for an extended period of time.

2.6 Mask Aesthetics

[0012] It is known that good mask aesthetics can be achieved by a sleek, simple design that does not have a 'busy' appearance. However, the various functional requirements of masks sometimes impinges on a designers ability to design a mask with good aesthetics. This problem can be compounded when masks are made from a relatively large number of components that do not connect in a smooth, contoured fashion.

BRIEF SUMMARY OF THE INVENTION

3.0 Embodiments of The Present Invention

[0013] Embodiments of the present invention seek to address one or more of the abovementioned problems or to at least provide a commercially valuable alternative.

[0014] One aspect of the invention relates to a method for manufacturing a respiratory mask wherein at least one step in the manufacturing process is the integral forming of at least two components in or from at least two different materials. Another aspect of the invention relates to a respiratory mask manufactured by the above method.

[0015] Preferably, the integral forming is an overmoulding operation which is automated, for example, by using robotics. Overmoulding may be performed by any known moulding technique, including surface treatment by any known treatment, such as plasma treatment. An overmoulding step may be used to mould a flexible component onto a component that is less flexible than the flexible material (henceforth a “substantially rigid component”). In one embodiment, the mask cushion (e.g., silicone) and frame (e.g., polycarbonate) are co-moulded using one of the manufacturing processes described herein.

[0016] As a result, it advantageously becomes possible to create a respiratory mask in which relatively complex geometries of the flexible components and of the substantially rigid components coupled to them can be realized. Furthermore, the relatively time-consuming and labour intensive mask manufacturing process can now be either partially or completely automated. This advantage arises because one or more mask assembly steps and mask components may not be required because two components (e.g. cushion and frame) are joined during moulding and so do not require subsequent assembly.

[0017] In an especially preferred embodiment of the invention, the integral forming of a flexible component onto a substantially rigid component is done directly in an injection moulding tool. This injection moulding tool preferably includes multiple cavities.

[0018] A liquid silicone rubber (LSR) material is preferably used for the flexible material and a polycarbonate plastic is preferably used for the substantially rigid material. In an especially preferred embodiment of the invention, the integral forming of the components is carried out in such a way that the flexible component can be manually separated from the substantially rigid component. This allows the flexible component to be removed as required. It is also possible to accomplish the integral forming such that the flexible component is coupled with the substantially rigid component in an intimately adhering way (i.e. the components cannot be manually separated).

[0019] In an especially preferred embodiment of the invention, at least one of the flexible components of the respiratory mask is a sealing cushion. The sealing cushion is preferably integrally formed onto the substantially rigid component in such a way that an intimate adhesive bond results. The bonding geometries of the substantially rigid component and the flexible components as well as other factors may be manipulated to provide a required level of adhesion.

[0020] According to another embodiment of the invention, there is provided a respiratory mask for administering a breathable gas to a patient, the respiratory mask comprising a) a first component formed from an elastomeric material; and b) a second component formed from a material that is less flexible than the elastomeric material, wherein the first component is integrally formed onto the second component.

[0021] According to another embodiment of the invention, there is provided a respiratory mask comprising a substrate made of a relatively rigid material, wherein the substrate includes at least one treated portion inclined to accept a reactive substance; and an elastomer that is made of a relatively more flexible material compared to the relatively rigid material of the substrate, said elastomer being applied to the substrate and secured to the substrate via an induced adhesive bond formed between said treated portion and a surface of the elastomer abutting the treated portion.

[0022] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask, comprising: providing an elastomeric material for forming into a first component; providing a second component that is less

flexible than the elastomeric material in a mould; and integrally forming the elastomeric material onto the second component within the mould in order to form the first component.

[0023] The first component can be manually separated from the second component, or the first component is joined to the second component in an intimately adhering manner. The method may further comprise pre-treating the second component to strengthen adhesion between the first and second components. The pre-treating step may comprise applying plasma, preferably an atmospheric gas plasma, to a bonding surface of the second component. Corona treatment is an alternative. The integral forming may be carried out in an injection moulding tool.

[0024] According to another embodiment of the invention, there is provided a mould for a respiratory mask for administering a breathable gas to a patient, the respiratory mask comprising a first component formed from an elastomeric material; and a second component formed from a material that is less flexible than the elastomeric material, wherein the first component is integrally formed onto the second component, wherein the mould comprises a mould cavity in which the first component is moulded onto the second component.

[0025] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame and an elbow provided to the frame, and wherein the elbow or frame includes at least one selected portion including said substrate, and the method further comprises overmoulding said elastomer onto the selected portion.

[0026] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame, a cushion provided to the frame and a forehead support positioned above the frame, wherein the mask comprises a flexible portion coupling the

frame and the forehead support, the flexible portion including a structural member including said substrate and at least one disc or tube including said elastomer.

[0027] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame made at least in part from said elastomer and a retaining ring including said substrate, wherein the method further includes overmoulding the frame onto the ring.

[0028] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask comprises a frame and a cushion and a headgear assembly to support the frame and cushion, wherein the headgear assembly includes a yoke associated with a strap and a seal ring provided to the yoke, wherein the yoke includes at least one selected portion including the substrate and the method comprises co-moulding the seal ring onto the yoke.

[0029] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a frame and a gas washout vent having at least one hole or pore, wherein the frame includes at least one selected portion including the substrate and the method comprises co-moulding the gas washout vent onto the frame.

[0030] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a frame having an aperture and a plug provided to close the aperture, the frame including at least a selected portion including said substrate and the method comprise overmoulding the plug onto the frame.

[0031] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a conduit including said substrate and a wall member formed at least in part by said elastomer, and said method further comprises overmoulding the wall member and the reinforcement member.

[0032] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the frame includes a port portion and a port cap provided to the frame, wherein the port portion includes at least a selected portion including the substrate and the method further comprises overmoulding the port cap onto the frame.

[0033] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein said mask includes a frame with said substrate and a bladder is provided to the frame and formed at least in part from said elastomer.

[0034] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a frame including at least one port, and nasal cannulae, wherein the frame includes said substrate and the cannulae are formed at least in part from the elastomer, the cannulae being in communication with the port.

[0035] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a frame, a cushion, a forehead support positioned above the frame, and a forehead pad provided to the forehead support, the forehead pad including said elastomer and the forehead support including said substrate.

[0036] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame including the substrate and a mask cushion including the elastomer, wherein the frame includes a peripheral region and the cushion includes a T-shaped or L-shaped rim overmoulded to the frame.

[0037] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame including the substrate and a mask cushion including the elastomer, in which the mask frame and the mask cushion form at least one of a diagonal joint, a lap joint and/or a V-joint.

[0038] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a frame and a cushion, the cushion having an expandable bladder having an interior defined by an interior surface of the elastomer and a portion of the frame that is not treated, and the frame includes a port to allow introduction of a substance delivered to the interior to expand the bladder.

[0039] According to another embodiment of the invention, there is provided a method for manufacturing a respiratory mask comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame a cushion and a cushion clip to secure the cushion to the frame, wherein the substrate is provided as part of the cushion clip and the cushion includes the elastomer.

[0040] According to another embodiment of the invention, there is provided a humidifier tub for a flow generator comprising a substrate made of a relatively rigid material, wherein the substrate includes at least one treated portion inclined to accept a reactive substance; and an elastomer that is made of a relatively more flexible material

compared to the relatively rigid material of the substrate, said elastomer being applied to the substrate and secured to the substrate via an induced adhesive bond formed between said treated portion and a surface of the elastomer abutting the treated portion wherein the humidifier tub includes a lid having said substrate and a seal made in part from said elastomer.

[0041] According to another embodiment of the invention, there is provided a method for manufacturing a humidifier tub comprising forming a substrate made of a relatively rigid material; and overmoulding an elastomer to or with the substrate, wherein the humidifier tub includes a lid having said substrate and a seal made in part from said elastomer.

[0042] According to another embodiment of the invention, there is provided a humidifier tub comprising a substrate made of a relatively rigid material; and an elastomer overmoulded with or to the substrate, wherein the humidifier tub includes a lid having said substrate and a seal made in part from said elastomer.

[0043] These and other aspects will be described in or otherwise apparent from the following detailed description of embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0044] Embodiments of the invention will now be described with reference to the accompanying exemplary drawings, in which:

[0045] Fig. 1 is a side, partial cross-sectional view of a respiratory mask according to a first embodiment of the present invention shown in situ on a patient's face;

[0046] Fig. 2 is a cross-sectional perspective view of a respiratory mask according to a second embodiment of the present invention;

[0047] Fig. 3 is a cross-sectional perspective view of an enlarged portion of the frame/ cushion interface of the respiratory mask of Fig. 2 and illustrates the bonding configuration therebetween;

[0048] Fig. 4 is a cross-sectional perspective view of an enlarged portion of the frame of the respiratory mask of Fig. 2 and illustrates an elastomer component disposed

over and bonded around a peripheral frame channel and in an inwardly disposed configuration;

[0049] Fig. 5 is a cross-sectional perspective view of an enlarged portion of the frame of the respiratory mask of Fig. 4 and illustrates the elastomer component in an outwardly disposed configuration;

[0050] Fig. 6 is a schematic, side, cross-sectional view of a cushion to frame connection according to a third embodiment of the present invention;

[0051] Fig. 7 is a side, partial cross-sectional view of the respiratory mask of Fig. 1 and illustrates the forehead pad in cross-section;

[0052] Fig. 8 is a side, partial cross-sectional view of the respiratory mask of Fig. 1 and illustrates a flexible portion between the frame and forehead support according to an embodiment of the present invention;

[0053] Fig. 9 is a side, partial cross-sectional view of a respiratory mask according to a fourth embodiment of the present invention and illustrates a flexible portion that incorporates a conduit section therethrough;

[0054] Fig. 10 is a perspective exploded view of a respiratory mask frame, elbow and elbow retaining clip according to a fifth embodiment of the present invention illustrating a bonded elastomer sealing portion on the elbow;

[0055] Fig. 11 is a perspective exploded view of a respiratory mask frame, elbow and elbow retaining clip according to a sixth embodiment of the present invention illustrating a number of additional bonded elastomer sealing portions on the socket and retaining clip;

[0056] Fig. 12 is a perspective exploded view of an elbow of a respiratory mask according to a seventh embodiment of the present invention illustrating a number of bonded elastomer sealing portions;

[0057] Fig. 13 is a perspective view of a portion of a respiratory mask frame and elbow according to a eighth embodiment of the present invention;

[0058] Fig. 14 is a perspective, cross-sectional view of the portion of the frame and elbow of Fig. 13;

[0059] Fig. 15 is an enlarged, perspective, cross-sectional view of the frame and elbow of Fig. 13 illustrating the elbow sealing arrangement;

[0060] Fig. 16 is a perspective view of a portion of a respiratory mask frame and elbow according to a ninth embodiment of the present invention;

[0061] Fig. 17 is a perspective, cross-sectional view of the portion of the frame and elbow of Fig. 16;

[0062] Fig. 18 is an enlarged, perspective, cross-sectional view of the elbow of Fig. 16 illustrating the elbow sealing arrangement;

[0063] Fig. 19 is a perspective, cross-sectional view of a portion of the respiratory mask frame and elbow of Fig. 16;

[0064] Fig. 20 is a perspective view of a portion of a respiratory mask frame and elbow according to an tenth embodiment of the present invention;

[0065] Fig. 21 is a perspective, cross-sectional view of the portion of the frame and elbow of Fig. 20;

[0066] Fig. 22 is an enlarged, perspective, cross-sectional view of the frame and elbow of Fig. 20 illustrating the elbow sealing arrangement;

[0067] Fig. 23 is a perspective view of a portion of a respiratory mask frame and elbow according to a eleventh embodiment of the present invention;

[0068] Fig. 24 is a perspective, cross-sectional view of the portion of the frame and elbow of Fig. 23;

[0069] Fig. 25 is an enlarged, perspective, cross-sectional view of the frame and elbow of Fig. 23 illustrating the elbow sealing arrangement;

[0070] Fig. 26 is a perspective view of a portion of a respiratory mask frame and elbow according to a twelfth embodiment of the present invention;

[0071] Fig. 27 is a perspective, cross-sectional view of the portion of the frame and elbow of Fig. 26;

[0072] Fig. 28 is an enlarged, perspective, cross-sectional view of the frame and elbow of Fig. 26 illustrating the elbow sealing arrangement;

[0073] Fig. 29 is a perspective view of a portion of a respiratory mask frame and elbow according to an thirteenth embodiment of the present invention;

[0074] Fig. 30 is a perspective, cross-sectional view of the portion of the frame and elbow of Fig. 29;

[0075] Fig. 31 is an enlarged, perspective, cross-sectional view of the frame and elbow of Fig. 29 illustrating the elbow sealing arrangement;

[0076] Fig. 32 is a perspective, exploded view of an elbow and a frame having a flexible enclosure, a rigid elbow connection ring defining an aperture in the frame and a rigid surrounding portion according to a fourteenth embodiment of the present invention;

[0077] Fig. 33 is a perspective, exploded view of an elbow, frame and headgear member according to a fifteenth embodiment of the present invention;

[0078] Fig. 34 is a side, partial cross-sectional view of a respiratory mask according to a sixteenth embodiment of the present invention and illustrates a vent;

[0079] Fig. 35 is a perspective exploded view of a respiratory mask frame and vent plug according to a seventeenth embodiment of the present invention;

[0080] Figs. 36(a)-36(d) are schematic diagrams showing three types of conduit reinforcing structure according to eighteenth, nineteenth, twentieth and twenty first embodiments of the present invention, respectively;

[0081] Fig. 37 is a side, cross-sectional view of a ports cap configured on a frame of a respiratory mask according to a twenty-second embodiment of the present invention;

[0082] Fig. 38 is a perspective, exploded view of a frame, elbow and elbow retaining clip including a plurality of gripping portions according to a twenty third embodiment of the present invention;

[0083] Fig. 39 is a perspective view of a frame including a large gripping portion according to a twenty-fourth embodiment of the present invention;

[0084] Fig. 40 is a perspective view of a frame including a detachable conduit arrangement according to a twenty-fifth embodiment of the present invention;

[0085] Fig. 41 is a perspective view of a flow generator including a humidifier tub having a lid according to a twenty-sixth embodiment of the present invention;

- [0086] Fig. 42 is a perspective view of the lid of Fig. 41 showing a recess configured to receive a seal;
- [0087] Fig. 43 is a perspective view of a lid seal for the lid of Fig. 41;
- [0088] Fig. 44 is a non-vented full face mask according to an embodiment of the present invention;
- [0089] Fig. 45 is a schematic cross-sectional view of a portion of Fig. 44 showing an elbow-to-frame interface/seal according to a first variant;
- [0090] Fig. 46 is a schematic cross-sectional view of a portion of Fig. 44 showing an elbow-to-frame interface/seal according to a second variant;
- [0091] Fig. 47 is a schematic cross-sectional view of a portion of Fig. 44 showing an elbow-to-frame interface/seal according to a third variant;
- [0092] Fig. 48 is a perspective view of an elbow having elastomer seals according to an embodiment of the present invention;
- [0093] Fig. 49 is an exploded perspective view of a test ring having a seal for insertion within a receptacle according to an embodiment of the present invention;
- [0094] Figs. 50-53 illustrate partial cross-sectional views of plug seals according to embodiments of the present invention; and
- [0095] Fig. 54 illustrates a schematic diagram of a mould system according to an embodiment of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS OF THE INVENTION

5.0 Introduction

5.0.1 Definitions

5.0.1.1 “Overmoulding”

[0096] The word “overmoulding” is used in this specification in its broadest sense, that is, in the sense of moulding one component onto another component, or

integrally forming two components. A number of different moulding processes that are deemed to fall within the ambit of the word 'overmoulding' as used in this specification are described below. It should be appreciated that this group of moulding processes is inclusive and not exhaustive.

[0097] Overmoulding is used to refer to the process of forming a bond between a first material, known as the "substrate material", and a second material known as the "overmould". However, the word 'overmoulding' also refers to moulding where **no bond** or substantive bond is formed but where respective components are held together, for example, only by a mechanical interlocking, keying or undercut. Mechanical interlocking can be either macroscopic (e.g., undercuts) or microscopic (e.g., depending on abrasion of the substrate).

[0098] The word 'overmoulding' also refers to a type of moulding where the two materials to be joined are **inserted into the mould at the same time** or at two points in time close together. For example, overmoulding includes **"overmoulding"** or **"co-injection moulding"**. A co-injection moulding process involves a first step where a first component (e.g., substrate) is moulded in a first mould and once ejected progresses to a second step where the first component is placed inside a second mould for the moulding of a second component (e.g., elastomer) on to it. In between the moulding steps, the first component may be treated to more readily accept a reactive substance. Treatment may take the form of plasma treatment, for example, and this treatment may take place within the mould(s) or outside the moulds. What distinguishes co-injection moulding from other types of overmoulding is that when the first component is being progressed through the second step another first component is being manufactured by the first step. That is, the first and second steps are being performed simultaneously for sequentially manufactured products. This can be achieved with a rotating tool set (e.g., a turntable with two or more moulding stations) or robotic arm.

[0099] 'Overmoulding' also refers to **"Moving Cores Moulding"** where one injection moulding machine fitted with two injection systems is used. Once the substrate has cooled sufficiently a section of the tool retracts, forming a cavity for the overmould

material. Moving cores have conventionally been best suited to simple overmoulds, where a uniform thickness of overmould is required.

[00100] “Rotating Platen or Stripper Plate” moulding is also considered a overmoulding process. This process involves rotation of the tool once the substrate has cooled. A rotating platen rotates the component on its core, whereas a rotating stripper plate lifts the component off its core before rotating. The main advantage of these methods is that they allow a different shaped cavity or core to be used to form the overmould. More sophisticated components can be created using this method.

5.0.1.2 “Flexible Material/ Component”

[00101] The words “flexible material/component” as used in this specification include any material with physical properties similar to or the same as an elastomer material which is defined in the Webster’s New World Dictionary as, “a rubber-like synthetic polymer, as silicone rubber”. Therefore, a rubber, a natural polymer or any other rubber-like material including some gels are included within the scope of the words “flexible material/component”.

[00102] The words “flexible material/component” also refer to various mixtures of individual elastomer components. These elastomers may be pre-mixed or mixed in the mould. Examples of elastomers are liquid silicone rubber (LSR), solid silicone rubber and thermoplastic elastomers (TPEs).

5.0.1.3 “Substantially Rigid Component”

[00103] A substantially rigid component includes all materials that are less flexible than the flexible material. Examples of substantially rigid components are polycarbonate (e.g. Lexan) and phenol formaldehyde (e.g. Bakelite.)

5.0.2 Bonding

[00104] There are 2 main types of bond: adhesive (an interfacial property) & cohesive (a bulk property). This application is largely concerned with the former rather than the latter.

[00105] There are several different types of adhesive bonding:

- adsorption bonding depends on intermolecular attractive forces between adhesive and substrate (e.g. Van der Waals forces)
- chemical bonding depends on available functional groups on the substrate surface and their reactivity with the molecules of the adhesive. Also known as covalent bonding.
- diffusion bonding depends on the mutual solubility between the substrate and adhesive
- electrostatic bonding depends (typically for solids) on dipole-dipole interactions.

[00106] Ideally, the adhesive strength of the bond formed in embodiments of the invention is significantly greater than the cohesive strengths of the components thereof. The level of adhesion achievable is dependant on the preparation of the bonding surface areas, amongst other factors. A pretreatment may be applied to a selected bonding area of the substantially rigid component to enhance adhesion.

[00107] One such pretreatment is the application of plasma, such as an atmospheric gas plasma, to the bonding area of the substrate. Plasma treatment chemically activates the bonding area to enhance chemical bonding. Plasma treatment is effected by blasting highly energized gases at the surface which causes reactive molecules to be embedded in the surface. These molecules form a bond with the relatively less rigid component, e.g., in the case of silicone, a polydimethyl siloxane bond may be formed. The gas is typically compressed air, but it can be nitrogen or other gases. It should be noted that the longer a plasma treated surface is left before bonding, the less effective the treatment will be. Plasma treatment is described in "Plasma Processes and Polymers" by d'Agostino et al., published by Wiley, 2005.

[00108] One method of applying plasma treatment is to position a masking sheet or stencil over the surface to which the plasma is to be applied. One or more aperture(s) in the stencil allows the plasma to contact the portion of the surface to be bonded but masks the remainder of the surface. An alternative to use of a masking sheet is the use of a finely controllable plasma gun (e.g. a gun mounted on an apparatus controllable by a computer such as a robotic arm).

[00109] Examples of commercially available atmospheric gas plasma guns include *Atomflo*TM by Surfx Technologies LLC of USA and *PlasmaTEC*TM by Dyne Technology Ltd of UK.

[00110] One alternative to plasma treatment is corona treatment, which typically is a stronger treatment which requires more energy and affects the substrate differently.

[00111] A further alternative to plasma treatment is chemically treating the surface by, for example, the application of adhesion promoters, such as silane coupling agents. Another chemical pre-treatment is the application of a solvent to the surface.

[00112] Yet another alternative is to use self-adhesive elastomeric material and to apply a non-bonding material (e.g. silicone grease) or contaminant, where a bond is not desired.

[00113] A further variation is flame oxidization of the surface.

[00114] Advantageously, all these pre-treatment processes allow treatment of only selected areas as required, by masking or otherwise avoiding areas where bonding is not desired.

[00115] Adhesion strength is also dependant on timing. A better bond may be formed when the second component is moulded onto the first component if the temperature of the first component is still raised. In the case that a chemical bond is not required, temperature differences and the resulting shrinkage differential may improve mechanical interlocking.

[00116] Often when an overmoulding process is used, the substantially rigid component will be moulded with a slight recess around the periphery of the bonding area to assist bonding with the flexible material by providing a level of mechanical

interlocking as well as a larger bonding area. Furthermore, bonding along multiple planes with respect to forces applied may assist in reducing adhesive failure.

5.1 General Structure of a Respiratory Mask

[00117] A respiratory mask 2A is shown in Fig.1 in situ on the face of a user 1000. The mask 2A comprises a frame 4A, formed from a substantially rigid component, such as a polycarbonate material, a sealing cushion 6A formed from an elastomeric material, such as liquid silicone rubber (LSR), and a forehead support 8A, which is adjustably coupled to the frame 4A via a flexible portion 10A. The forehead support 8A includes a forehead pad 12A, made from an elastomeric material.

5.2 Sealing Cushion

[00118] The cushion 6A has been co-moulded onto a peripheral portion 14A of the frame 4A. In this example, the frame 4A was pretreated such that the cushion 6A forms a high-strength adhesive bond with the frame 4A.

[00119] The cushion 6A includes a lip 16A that is curved inwardly and terminates in an aperture 18A that is sized and shaped for receiving at least part of the nose of a patient. The lip 16A traverses an upper lip region 1002 of the user 1000 in the case that the mask 2A is configured as a nasal mask or a chin region 1004 of the user 1000 in the case that the mask 2A is configured as a full-face mask. Although the mask 2A only incorporates a single lip 16A, it should be appreciated that multiple lips could be incorporated. Gel structure(s) may also be incorporated into lip 16A, or in the case that multiple lips are provided into each lip. Alternatively, the lip 16A could be replaced with one or more gel structures.

[00120] Moulding the cushion 6A to the frame 4A eliminates the need for a cushion-to-frame securing component and the associated assembly step. This reduces the cost of goods and/or may assist in improving compliance with therapy.

5.2.1 Bonding Configurations

[00121] Various bond configurations are possible. In one embodiment, shown in Figs 2 and 3, the cushion 6B of a respiratory mask 2B has a T-shaped rim 20B that is sized to be bonded to a peripheral region 22B of the frame 4B. The T-shaped rim 20B provides a bonding surface 24B that is larger than it would otherwise be if no T-shaped bonding rim 20B was provided. This larger bonding surface 24B allows a stronger bond to form. Alternatively, an L-shaped bonding rim could be provided. However, the T-shaped bonding rim 20B is advantageous with respect to the L-shaped rim because when the cushion 6B is pulled away from the frame 4B, no bending moment is created. A bending moment could assist a tear developing through the bond. Other suitable bonding configurations include a diagonal joint, a lap joint and a V-joint. Furthermore, the bonding could occur on an interior surface of frame 4B, e.g., a lap joint.

5.2.2 Bonding to Form Bladders

[00122] Referring to Figs 4 and 5, selective bonding can be utilized to form a bladder 26B that can be expanded. The bladder 26B can be expanded by delivery of pressurized air to a port 30B. The stenciling or masking procedure described in Section 5.0.2 may be utilized to chemically activate bonding areas 32B where sides of the wall 34B of the bladder 26B join the frame 4B. The bonding areas 32B adhere to the portions of the cushion in contact with the bonding areas, while the surface of the bladder 26B is free to separate from the frame 4B since those portions of the frame have not been treated. The pressurized air may be pressurized to 2 bar or any other suitable pressure. Furthermore, gases other than normal air could be used to pressurize the bladder 26B. Alternatively, a gel, foam, liquid or other soft substance may be inserted into the bladder 26B instead of a gas, such that a soft, flexible pad is formed. The pad may be filled and permanently sealed or be releasably or temporarily sealed. The inside surfaces of the pad may be provided with a permeation-resistant liner.

[00123] In one embodiment, the gel cushion could be provided using a skin made of LSR that is filled with a gel, e.g., silicone. To prevent the gel from permeating

through the LSR skin, the inside surface of the skin could be coated with a liner, such as polyester and/or polyurethane. The liner could be applied using any number of techniques, e.g., spraying (just before the gel is introduced, e.g., in Fig. 5), co-moulding, dipping, brushing, etc.

[00124] Referring to Fig 6, an alternative reinforced bladder arrangement 36C is shown. In this arrangement the cushion 6C is not directly formed onto the frame 4C but is co-moulded to a clip 38C. The clip 38C is attachable to the frame 4C by a mechanical interlock. The cushion 6C may also be bonded to the clip 38C in a manner such that when attached to the frame 4C, a portion of the cushion 6C is sandwiched between the frame 4C and clip 38C providing a mechanical interlock. The clip 38C is configured with a reinforcing member 40C for supporting and stabilizing an under surface 42C of the cushion 6C. This limits rotation/ movement of the cushion 6C on the face of the user.

5.3 Forehead support

[00125] Referring now to Fig 7, the forehead support 8A and forehead pad 12A may be embodied as co-moulded components. The forehead pad 12A is formed by injection-moulding an elastomeric material onto the forehead support 8A which is made from a dimensionally stable plastic material, such as a polycarbonate. A slot 44A is formed in the forehead pad 12A during the overmoulding process by virtue of the shape of the forehead support 8A. The slot 44A provides a mechanical interlock such that the forehead support 8A can be releasably secured to the forehead support 8A. There is no intended or significant adhesive bond between the forehead support 8A and forehead pad 12A in this embodiment. This may be achieved by not using a surface pre-treatment and/or overmoulding the parts once the forehead support 8A is completely set (i.e. after moulding). The benefit of not including a substantive bond in this instance is that the forehead support can be removed for separate cleaning or replaced with a new or different type of forehead support.

[00126] Advantageously, overmoulding the forehead pad 12A to the forehead support 8A eliminates the assembly step of mounting the forehead pad 12A to the

forehead support 8A, reducing the cost of goods and increasing convenience to the patient.

5.4 Flexible portion

[00127] The flexible portion 10A will now be described with reference to Fig 8. The flexible portion 10A comprises a structural spine 50A and a number of elastomer discs 52A that have been co-moulded onto the spine 50A and between the frame 4A and the spine 50A. Because the elastomer discs 52A are flexible, the frame 4A is able to articulate with respect to the forehead support 8A. The elastomer discs 52A may be made from the same elastomer material that the cushion 6A is made out of or from a different flexible material. In an alternative embodiment the elastomer discs 52A comprise bladders formed from an elastomeric material (or otherwise) that are filled with a compressed gas, liquid or soft solid such as foam, gel or mineral particles.

[00128] Fig 9 shows another embodiment of a mask 2D having a flexible portion 10D including an elastomer tube 56D around which a less flexible exoskeleton 58D is disposed. The ends 60D & 62D of the elastomer tube 56D have been comoulded to the frame 4D and forehead support 8D, respectively. This arrangement allows the frame 4D to articulate with respect to the forehead support 8D, and consequently, the cushion 6D to rotate and move to a degree with respect to the patient's face. This means that the mask 2D is able to provide a better seal against the patient's face. This elastic deformation behavior can be varied by changing the wall thickness or wall section of the exoskeleton 58D.

[00129] The elastomer tube 56D may be made from the same elastomer material that the cushion 6D is made out of or from a different flexible and co-mouldable material.

[00130] In this case, the elastomer tube 56D provides a fluid passageway that extends between an inner region of the frame 4D and the forehead support 8D where the fluid passageway terminates in a connection 66D. The connection 66D is adapted for receiving one end of a conduit (not shown) that is in fluid communication with an outlet port of a flow generator (not shown).

[00131] A mask in accordance with other embodiments of this invention may include a translatable adjustment rather than a rotatable adjustment.

5.5 Elbow & Frame Socket

[00132] Referring to Fig 10, a mask 2E is shown which has a frame 4E that comprises a socket 68E that is adapted to receive a first end 70E of an elbow 72E. The first end 70E of the elbow 72E is swivel mounted to the socket 68E and the elbow 72E provides fluid communication between a conduit (not shown) and the mask 2E. A clip 74E is provided to the first end 70E of the elbow 72E to retain it in the socket 68E in use.

[00133] In Fig 10 the second end 76E of the elbow 72E has an elastomer portion 76E co-moulded thereto to provide an improved connection and seal with the conduit to which it is attached. In an alternative embodiment (not shown), the conduit has an elastomer sealing portion rather than the second end 76E.

[00134] Referring to Fig 11 the socket 68G has a dimensionally rigid material portion 78G and an elastomer portion 80G co-moulded onto an inner surface thereof. The elastomer portion 80G provides a better seal with the first end 70G of the elbow 72G in use. The clip 74G also includes an elastomer portion 88G co-moulded thereon. This provides a more acoustically pleasing clipping sound.

[00135] Fig. 12 illustrates an elbow 72H generally similar in design and construction to the elbow of Figs 10 & 11 in its component parts. The elbow 72H features a number of elastomer portions 90H that serve to aid sealing, dampening, the reduction of rattle and/or the tactility and acoustics of connecting parts.

[00136] A number of different elbow-to-frame sealing arrangements will now be described. These are suitable for use on a variety of masks. Following this a sealing elbow arrangement for the ResMed *Meridian* mask [U.S. Provisional Patent Application No. 60/682827] and a sealing arrangement for the ResMed *Swift* mask [U.S. Provisional Patent Application No. 60/734282] will be described, each incorporated by reference in its entirety.

5.5.1 Two Stage Radial Elbow to Frame Seal A

[00137] Figs. 13 to 15 show a two stage radial seal 92I comoulded to an elbow 72I and adapted to seal against a frame 4I. The seal 92I comprises a long elastomer lip 94I that abuts an inner surface 84I of a socket 68I of a frame 4I. The seal 92I further comprises two shorter lips 96I that are moulded in the line of draw. In use, the long lip 94I presses into the socket 68I and flexes back onto the two shorter lips 96I such that the long lip 94I is supported in a position where it abuts and seals against the socket 68I. This geometry accommodates misalignment of the elbow 72I with respect to the frame 4I.

[00138] The elbow 72I further incorporates three circumferential flanges. A first flange 98I is integrally moulded to the elbow 72I to prevent the seal 92I from contacting any flat supporting surface when the elbow 72I is disassembled from the frame 4I. This minimises risk of damage to the seal 92I during transport, storage and cleaning. A second flange 100I is provided on the elbow 72I and engages the socket 68I to stabilize the elbow 68I. While in this embodiment the second flange 100I is located inboard from the seal 92I, in other embodiments it could be moved outboard providing a greater moment arm. A third flange 102I is positioned within the socket 68I to engage a shoulder 103I of the elbow 4I, adjacent where the socket 68I begins to extend beyond the outer surface 104I of the frame 4I.

[00139] Another embodiment (not shown) is also provided where only a line contact seal is provided to the frame 4I as opposed to an area contact seal. A line contact seal reduces the torque required to rotate the elbow with respect to the frame.

[00140] It should also be noted that this design avoids undercuts and crevices to ensure ease of cleaning.

[00141] Fig. 13 also depicts an anti-asphyxia valve having a base portion 103I that is co-moulded to an elbow clip 105I of the elbow 72I. This overmoulding step replaces an assembly step reducing the cost of goods and increasing convenience to the patient.

5.5.2 Two Stage Radial Elbow to Frame Seal B

[00142] The embodiment shown in Figs 16 to 19 includes a seal 106J that is similar to the seal 92I of Figs 13-15 except that the seal geometry has been altered to provide less contact area between the seal 106J and the frame 4J. The seal 106J comprises a long elastomer lip 94J and one shorter lip 96J that are moulded in the line of draw. The long lip 94J presses into the socket 68J of the frame 4J and flexes back onto the shorter lip 96J such that the long lip 94J is supported in a position abutting and sealing with the inner surface 84J of the socket 68J. This geometry accommodates misalignment of the elbow 72J with respect to the frame 4J.

[00143] The elbow 72J incorporates three circumferential flanges to stabilize the elbow 72J within the socket 68J. A first flange 98J is positioned outside the socket 68J and frame 4J. The first flange 98J prevents the seal 106J from contacting any flat surface when the elbow 72J is disassembled from the frame 4J thereby reducing the risk of damage to the seal 106J during transport, storage and cleaning. A second flange 100J is positioned outside the socket 68J and inside the frame 4J and abuts the socket 68J to stabilize the elbow 68J. A third flange 102J is positioned within the socket 68J adjacent where the socket 68J begins to extend beyond the outer surface 104J of the frame 4J.

[00144] Another embodiment (not shown) is also provided where only a line contact seal is provided to the frame 4J as opposed to an area contact seal. A line contact seal reduces the torque required to rotate the elbow with respect to the frame.

[00145] This design avoids undercuts and crevices to ensure ease of cleaning.

5.5.3 Single Radial Seal

[00146] Referring to the mask 2K of Figs 20-22 an elbow 72K is provided having a single radial lip seal 108K that acts on an inner surface 84K of a socket 68K. The elbow 72K incorporates four circumferential flanges to support and stabilize the elbow 72K on the frame 4K. A first flange 98K is positioned outside the socket 68K and frame 4K. A second flange 100K is positioned outside the socket 68K and inside the frame 4K. A third and fourth flange, 102K & 110K respectively, are positioned on either side of the seal 108K. This design avoids undercuts and crevices to ensure ease of cleaning.

5.5.4 Double Radial Seal

[00147] Figs 23 to 25 show a mask 2L incorporating a double radial seal 112L. The double radial seal 112L has two lips 114L & 116L, respectively, adjacent each other, that seal against an inner surface 84L of a socket 68L of a frame 4L. Each lip 114L, 116L is configured with a generally triangular cross-section such that it has a degree of stiffness to enhance sealing.

[00148] The elbow 72L incorporates three circumferential flanges 98L, 100L & 102L that are arranged in the same fashion as the embodiment of Section 5.5.1 and Figures 13-15. This design avoids undercuts and crevices to ensure ease of cleaning.

5.5.5 External Seal

[00149] The embodiment shown in Figs 26-28 provides 3 sealing zones between the elbow 72M and the socket 68M. The 3 sealing zones include a radial seal 114M disposed on the elbow 72M inside the socket 68M, an axial seal 116M that seals against an end face 118M of the socket 68M and an external radial lip seal 120M that seals against an outside the socket 68M.

[00150] The elbow 72M incorporates four circumferential flanges 98M, 100M, 102M and 103M to stabilize and support the elbow 72M within the socket 68M. Additionally, the first flange 98M of the circumferential flanges is sized and adapted to prevent the seal 120M from contacting any flat supporting surface when the elbow 72M is disassembled from the frame 4M. This minimises risk of damage to the seal 120M during transport, storage and cleaning.

5.5.6 Radial & Axial Seal Combination

[00151] Referring to Figs 29-31 a sealing arrangement 122N is shown. The sealing arrangement 122N comprises a radial lip seal 124N of triangular cross-section that seals against an inner surface 84N of the socket 68N and an axial lip seal 126N that seals against an end face 118N of the socket 68N.

[00152] The elbow incorporates the same arrangement of three circumferential flanges for stabilization of the elbow 72N within the socket 68N as is provided in the embodiment of Figs 13-15 described in Section 5.5.1.

5.5.7 ResMed Meridian Mask [US Patent Application No. 60/682827]

[00153] The contents of US Patent Application No. 60/682827 are incorporated herein by reference in their entirety. Referring to Fig 32, the *ResMed Meridian Mask* Assembly 2O comprises a flexible silicone frame 4O having a hard peripheral portion 127O, a polycarbonate elbow 72O and a retaining ring 128O that is used to connect the frame 4O to the elbow 72O and allow them to swivel relative to each other.

[00154] The elastomer frame 4O can be overmoulded to the retaining ring 128O. This ameliorates any difficulties encountered in mounting the ring 128O on the frame 4O and takes away the step of connecting the two parts during assembly.

5.5.8 ResMed Swift Mask Elbow [US Patent Application No. 60/758200]

[00155] The contents of US Patent Application No. 60/758200, filed January 12, 2006 are incorporated herein by reference in their entirety. Referring to Figure 33, a portion of a *ResMed Swift Mask* 2P is shown including a cushion assembly 6P, yoke 130P that is attached to a headgear strap, seal 132P and elbow 72P. The yoke 130P includes a yoke ring 134P that is adapted to surround a portion of the seal 132P and the seal 132P is adapted to surround a portion of the elbow 72P. The cushion assembly 6P may be adjustably rotated with respect to the yoke 130P.

[00156] Seal 132P may be overmoulded to the yoke ring 134P. This ameliorates difficulties sometimes encountered in mounting the seal 132P on the yoke ring 134P and takes away the step of connecting the two parts during assembly.

5.6 Gas Washout Device

[00157] Referring to Fig 34, the frame 4P includes a co-moulded vent 54P for allowing exhaled breath to exit an interior region of the frame 4P into the surrounding environment. The vent 54P is formed from an elastomer material that has been co-moulded to the frame 4P. The geometry of the frame 4P and vent 54P are such that they mechanically engage in a manner that allows the vent 54P to be retained or removed from the frame 4P, as required.

[00158] In another embodiment, the vent 54P is substantially inseparably coupled to the frame 4P by a chemical bond in addition to the mechanical interlock. The vent may also be embodied as an insert that comprises a plurality of fluid conduits (or vent holes or pores (e.g., sintering)) that connect the interior region of the frame 4P to the surrounding environment.

5.6.1 Sealing a Vented Mask to Make a Non-Vented Mask

[00159] Fig 35 depicts a vented mask 2Q having a vent aperture 54Q and a plug 136Q. For ease of visualization Fig 35 shows the plug 136Q separately from the mask 2Q but in reality the plug 136Q is formed in the vent 54Q by overmoulding to form a non-vented mask. In this case, the plug 136Q is formed from silicone.

[00160] This process means that a single mask frame 4Q is a suitable component for either a vented or a non-vented mask. This reduces manufacturing costs because only one frame 4Q needs to be moulded for both types of mask.

[00161] In the case that non-vented therapy is being delivered to a patient, the plug 136Q is permanently attached to the frame 4Q. Advantageously, this avoids user interference with the equipment (e.g. removal of the plug 136Q) and subsequent therapy problems. This permanent attachment may be achieved through the aforementioned plasma pre-treatment. Alternatively, the plug 136Q may be temporarily attached, and in this case the mask 2Q could be used to provide either vented or non-vented therapy.

5.7 Conduit

[00162] Methods of conduit manufacture utilizing overmoulding will now be described. The fundamental technical issues addressed by the overmoulding technique in the context of conduits is the development of a conduit which is both flexible yet does not occlude in use. Overmoulding allows a flexible membrane conduit wall to be attached or bonded to a less flexible conduit structure, the purpose of which is to prevent occlusion of the flexible wall.

[00163] In one embodiment, the conduit structure is configured as a reinforcement structure, e.g., an exoskeleton over/within, and/or inside the flexible conduit wall. Clearly, where the conduit structure extends continuously along the conduit wall, the conduit structure must be formed of a flexible material to allow the conduit to bend. Fastening of the flexible wall to the conduit structure may be achieved by either mechanical engagement, molecular bonding or both.

[00164] Three embodiments of conduit structures are shown in Figs. 36(a)-36(c). The first, shown in Fig 36(a), is a helical conduit structure 140S that provides significant torsional strength. The second conduit structure 140T, shown in Fig 36(b), comprises a plurality of circular ribs 142T interconnected by longitudinal members 144T that are provided on alternating opposing sides of the conduit wall (not shown). Fig 36(c) depicts a third conduit structure 140U comprising a plurality of circular ribs 142U interconnected by dual longitudinal members 144U that are provided on opposing sides of the conduit wall (not shown). Fig 36(d) depicts a fourth conduit structure 145.

5.8 Ports Cap

[00165] Fig. 37 shows a ports cap 146V co-moulded to the frame 4V. The ports cap 146V comprises a cover portion 148V and a hinge portion 150V that is permanently bonded to an adhesion region 152V of the frame 4V. The cover portion 148V is only lightly or marginally bonded to the frame 4V and can be readily manually separated by a user or clinician the first time the ports cap 146V is used. Advantageously, the ports cap 146V cannot be dropped by a patient or lost. The ports cap 146V can be designed so that

it can be reattached to the frame 4V even though the light bond is broken (e.g. by a mechanical interlock such as a rib and groove arrangement).

5.9 Mask Surfaces

5.9.1 Gripping

[00166] Manual gripping of mask parts made of hard materials with smooth surfaces (e.g. polycarbonate) can be difficult. This can lead to slippage or movement during manipulation of mask parts. The integration of elastomeric regions onto a mask, and in particular onto a mask frame, assists both manual and robotic gripping. Elastomeric regions may be integrated into a mask solely for this purpose and may provide robots with a controlled grip to handle mask parts for automation, assembly or packaging purposes.

[00167] An example of how gripping regions might be incorporated into a mask frame 4W and elbow 72W is illustrated in Fig 38. A number of small gripping regions 152W are co-moulded onto each side of the frame 4W and at least one relatively large gripping region 154W is co-moulded onto each side of the elbow 72W. The elbow gripping regions 72W assist: (1) gripping of the elbow 72W during manufacture, and/or (2) removal of the elbow 72W from the frame 4W by a patient or clinician.

5.9.2 Soft Touch

[00168] Other mask embodiments include one or more soft touch surface(s) co-moulded to the mask frame. The soft touch surface(s) feels nicer and less clinical to a patient than a hard surface(s) (e.g. polycarbonate). By varying the thickness and hardness of a soft touch surface, a range of different feels may be provided. Other parts of respiratory masks may also include soft touch surfaces such as the headgear clips or forehead support.

5.9.3 Branding

[00169] Co-moulded elastomer regions also provide suitable surfaces for the placement of product or company branding or logos, e.g., “ResMed” could be spelled out by co-moulding onto various mask components such as the frame, headgear, forehead support, elbow, etc. In one embodiment, the branding indicia is embossed into the elastomer or the elastomer forms the branding indicia. It should be noted that any one elastomer region could be used for a multiplicity of purposes, such as more than one of gripping, soft touch and branding. The elastomer could also be coloured to improve aesthetics, or for branding purposes etc.

5.10 Other Overmoulding Applications for Masks

5.10.1 Mask Volume Reduction Bladder

[00170] Referring to Fig 39, a mask volume reduction bladder (MVRB) 156Y may be incorporated into a mask frame 4Y by overmoulding an expandable pocket onto an interior surface 158Y of the frame 4Y, and more particularly, overmoulding a peripheral edge 160Y of the pocket to the interior surface 158Y of the frame 4Y. The bladder 156Y is positioned and configured such that it is expandable to occupy at least a portion of the gas dead space within the mask. In this particular embodiment, the bladder walls are made from a thin sheet of silicone (0.1 – 0.6 mm thick).

[00171] The bladder may have elastic properties and in an alternative embodiment may be configured within a recess in the frame instead of on an interior surface of the frame. In one variation, the bladder volume is in fluid communication with an interior volume of the frame via a flap valve or other suitable valve. In yet another variation, the frame includes an air passageway between the interior volume of the frame and the interior volume of the bladder.

[00172] In another embodiment, the bladder inflates and deflates responsive to the breathing cycle of the patient, reducing the volume required to be displaced by the patient’s lungs during exhalation. In yet another embodiment, the bladder deflates during exhalation to increase the volume and thus reduce the expiration pressure peak and

subsequently the work of breathing. In another embodiment the bladder is co-moulded to an outer surface of the frame and an interior portion of the bladder is in fluid communication with an inner region of the frame (e.g. via an aperture in the frame). During exhalation the bladder can expand and thus reduce the expiration pressure peak and subsequently the work of breathing.

5.10.2 Removable Oxygen Sensing Cannula

[00173] Fig 40 shows a frame 4Z of a respiratory mask incorporating oxygen cannulae 162Z that are formed by overmoulding silicone to an interior surface of the frame 4Z. The cannulae 162Z can be peeled away from the frame 4Z starting at the cannula exit apertures 164Z such that the exit apertures 164Z are positioned directly beneath a patient's nares. The cannulae 162Z are in fluid communication with frame ports 166Z to which an oxygen delivery conduit (not shown) or gas receiving conduit (not shown) may be attached. A gas receiving conduit might be used to receive exhaled breath in order to detect levels of different gases (e.g. oxygen) in the exhaled breath. The frame ports 166Z are sealed by plugs when the cannulae 162Z are not in use and the cannulae 162Z may be completely removed (torn off) the frame 4Z. The plugs may take the same or similar form to those described in Section 5.8.

5.10.3 Humidifier Tub Seal [US Patent Application No. US 10/533940]

[00174] US Patent Application No. US 10/533940 is incorporated herein by reference in its entirety. Referring to Figs 41-43, a *ResMed* S8 flow generator 168AA is shown comprising a humidifier 170AA. The humidifier 170AA has a lid 172AA, an underside of which is shown in Fig 42 and includes a recess 174AA. Fig 43 shows an elastomer seal 176AA that is adapted to fit in the recess 174AA.

[00175] The improvement over US Patent Application No. US 10/533940 is that the elastomer seal 176AA is co-moulded to the lid 172AA about the air exit aperture 178AA. This overmoulding provides a stronger mounting of the seal 176AA to the lid 172AA than a mere mechanical interlock and also ameliorates the problem of biological

growth in crevices. The overmoulding can be in the form of a full surface bond or a peripheral bond.

[00176] The improvement ameliorates difficulties sometimes encountered in mounting the seal 176AA on the lid 172AA and makes the step of connecting the two parts during assembly obsolete.

5.11 Elbow-to-Frame Seal

[00177] Fig. 44 shows a full face mask 2.1 having a frame 2.2 and an elbow 2.3 provided to the frame. Details of the overall mask are described in relation to U.S. Patent Application No. 11/027,689, filed January 3, 2005, incorporated herein by reference in its entirety. A seal is formed between the elbow and the frame and may be formed on the frame or the elbow using the overmoulding techniques described herein.

[00178] Fig. 45 shows a seal 2.5 that is formed on an inner circumferential portion of the elbow at the base of the frame inlet. Fig. 46 shows a seal 2.6 formed on an outer circumferential surface of the elbow. Fig. 47 shows a seal 2.7 at the distal end portion of the inlet portion of the frame.

[00179] Fig. 48 includes an elbow with the seals from Figs. 47 and 46. All of the seals 2.5, 2.6 and 2.7 can be formed on either the frame and/or the elbow. The seals help decrease leak while at the same time reduce squeak/squeal if the elbow is rotated relative to the frame.

5.12 Alternative Seal Designs

[00180] Fig. 49 is an exploded view of a test rig 3.1 including for testing seals that can be used with the elbow-to-frame connections described above. Figs. 50-53 illustrate various seal geometries.

[00181] Fig. 50 shows a syringe-type seal 3.2 that is compressed to fit within the bore, but provides high sealing strength. Fig. 51 shows a blade style seal 3.3. While the main ridge 3.4 contacts the bore, the adjacent portions 3.5 may also contact the bore depending on the desired amount of rotation force required. Fig. 52 shows an axial flap

seal 3.6 that engages on an angled face 3.7 of the bore. Fig. 53 shows a rubber seal having a generally rectangular cross-section.

5.13 Mould

[00182] A mould for a respiratory mask or humidifier tub is provided in one embodiment of this invention. The substantially rigid component mould provides the substantially rigid component with very small sealing rims around the periphery of the elastomer bonding region and the elastomer mould has corresponding notches that form a tortuous path that is difficult for the liquid elastomer or other material to flow through. Fig. 54 shows a sample rotating mould system 4.1 having a turntable 4.2 that rotates about an axis 4.3. Turntable 4.2 includes a first moulding station 4.4 for moulding a first component, e.g., the substrate (e.g., frame) and a second moulding station 4.5 for moulding a second component, e.g., the elastomer (e.g., cushion, pad, seal, etc.).

5.13.1 Mask Design to Facilitate Removal from Mould

[00183] The respiratory mask is designed such that its substantially rigid components can be demoulded largely without undercuts. The elastomer components may be made by moulding tool structures that produce undercuts. The demoulding of the elastomer components can then be done by elastic deformation of the elastomer components.

5.14 Fully Automated Mask Manufacture

[00184] An automated manufacturing process for a mask is another embodiment of this invention. The automated manufacturing process utilizes overmoulding to manufacture and/or bond appropriate components, in combination with at least one automated assembly step (e.g. fitting the elbow in the socket or attaching the headgear to the headgear clips).

5.15 Advantages

5.15.1 Cost Saving

[00185] Overmoulding reduces cost of goods. Components, the only function of which is to hold two other components together are made redundant. Components can also be made from less material when the attachment structure is no longer needed.

[00186] To raise an order with a supplier costs money. There is the cost of the labour of the purchasing officer, as well as the cost of transporting each individual part to the company. Overmoulding allows companies to combine two or more components into one, thus significantly reducing the associated purchasing costs.

[00187] Overmoulding also reduces inventory costs. These are the costs a company incurs to keep the components in its warehouse and then deliver them to the production floor. In simple terms, half as many parts means half as many transactions. Warehousing staff also have one less part to receive into stores and one fewer part to locate and move.

[00188] A mask with less parts also provides further cost savings by reducing the amount of time it takes to assemble the finished product and/or the number of assembly steps. Overmoulding also eliminates secondary operations such as machining and use of adhesives.

5.15.2 Quality Improvement

[00189] Improving quality leads to further cost savings. For example, the cost of rework which includes the cost of any materials scrapped, plus the cost of employing a worker to repair or replace a component may be avoided.

[00190] An automated overmoulding operation would reduce assembly errors since fewer manual assembly steps are required.

[00191] Quality derived through use of overmoulding also reduces costs in terms of reducing disgruntled customers. For example, the often difficult step of assembling a cushion to a frame utilizing a cushion-to-frame clip is avoided.

5.15.3 Sealing

[00192] Since flexible materials seal better than harder materials, the use of flexible materials to surface harder materials will allow better seals to be formed. For example, improved sealing between the elbow and frame, and frame and cushion can be achieved.

5.15.4 Soft-Touch

[00193] A soft to touch surface generally feels nicer and less clinical than a hard surface to a patient. Varying both the co-mould thickness and hardness can produce a range of different feels.

5.15.5 Biological contamination can be removed by washing

[00194] Mask components that have been co-moulded according to some embodiments of the invention can have biological contamination removed therefrom by washing the mask. The reason for this is that the components are integrally joined and thus the mask does not include any crevices that cannot be cleaned within the normal course of washing.

5.16 Materials

[00195] Thermoplastic elastomers (TPEs), solid silicone rubbers and Liquid Silicone Rubbers (LSRs) are usually suitable materials for a flexible co-mould. It has been found by the inventors that a thermoplastic elastomer with the following general properties may be particularly advantageous:

- Hardness of approximately 40 ShoreA
- High Tear strength
- Resistance to cleaning chemicals (e.g. soap, detergents etc.)
- Low compression set
- Ability to withstand cleaning temperatures of 93 degrees Celsius
- Low friction and low squeak

- Biocompatibility (specifically– ISO 10993, parts 3, 5, 6, 10 &11)
- Good bonding to substantially rigid component
- Good process control for high volume manufacture
- Translucency
- Low cycle time

[00196] The following materials have been found to exhibit some or all of the above properties:

- “Dynaflex® TPE Compounds” and “Versalloy®” made by GLS
- “Santoprene™ Thermoplastic Vulcanizate” and “Santoprene™

Thermoplastic Vulcanizate” made by Advanced Elastomer Systems.

- Silastic™ Silicone rubbers made by Dow Corning.
- Elastosil™ Silicone rubbers made by Wacker.

[00196] Where solid silicone rubbers are used, resin transfer moulding techniques may be used for moulding of the flexible components.

[00197] Polycarbonate, polypropylene, trogamid (nylon) and pocan plastics are all suitable substantially rigid materials.

5.17 Other Variations

[00198] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. For example, any functionally suitable materials may be utilized in conjunction with this invention. Furthermore, the flexible and substantially rigid materials could have the same level of flexibility or

resilience. In another embodiment, the substantially rigid material could be more flexible than the flexible material.

[00199] Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments, or additional embodiments can reside in a single element or portion thereof of any given embodiment.

[00200] In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

CLAIMS:

1. A respiratory mask for administering a breathable gas to a patient, the respiratory mask comprising
 - a) a first component formed from an elastomeric material; and
 - b) a second component formed from a material that is less flexible than the elastomeric material, wherein the first component is integrally formed onto the second component.
2. The respiratory mask as claimed in claim 1, wherein the integral forming is such that the first component can be manually separated from the second component.
3. The respiratory mask as claimed in claim 1, wherein the integral forming is such that the first component is joined to the second component in an intimately adhering manner.
4. The respiratory mask as claimed in claim 1, wherein the integral forming is carried out in an injection moulding tool.
5. The respiratory mask as claimed in claim 1, wherein the elastomeric material is an LSR material.
6. The respiratory mask as claimed in claim 1, wherein the second component is formed from a polycarbonate material.
7. The respiratory mask as claimed in claim 1, wherein the first component is a sealing cushion.

8. The respiratory mask as claimed in claim 1, wherein the first component is an outlet conduit device.
9. The respiratory mask as claimed in claim 1, wherein the first component is a forehead-contacting device.
10. The respiratory mask as claimed in claim 1, wherein the first component is a closure device.
11. The respiratory mask as claimed in claim 1, wherein the first component is an articulated structure.
12. The respiratory mask as claimed in claim 1, wherein the first component is a diaphragm device.
13. The respiratory mask as claimed in claim 1, wherein the first component is a tubular body portion.
14. The respiratory mask as claimed in claim 1, wherein the first component is a breathing gas line segment.
15. The respiratory mask as claimed in claim 1, wherein the first component is a functional seal.
16. The respiratory mask as claimed in claim 1, wherein the first component is a stop device.
17. The respiratory mask as claimed in claim 1, wherein the first component is a decoration or logo.

18. The respiratory mask as claimed in claim 1, wherein the first component is a headband connection device.
19. The respiratory mask as claimed in claim 1, wherein the first component is a soft gripping pad.
20. The respiratory mask as claimed in claim 1, wherein the second component is a forehead rest mount.
21. The respiratory mask as claimed in claim 1, wherein the second component is a mask frame.
22. A method for manufacturing a respiratory mask, comprising:
 - providing an elastomeric material for forming into a first component;
 - providing a second component that is less flexible than the elastomeric material in a mould; and
 - integrally forming the elastomeric material onto the second component within the mould in order to form the first component.
23. The method as claimed in claim 22, wherein the first component can be manually separated from the second component.
24. The method as claimed in claim 22, wherein the first component is joined to the second component in an intimately adhering manner.
25. The method as claimed in claim 22, wherein the first component is joined to the second component in both a separable manner and an intimately adhering manner, in different places.

26. The method as claimed in claim 24, further comprising pre-treating the second component to strengthen adhesion between the first and second components.
27. The method as claimed in claim 26, wherein the pre-treating step comprises applying plasma to a bonding surface of the second component.
28. The method as claimed in claim 27 wherein the plasma is an atmospheric gas plasma.
29. The method as claimed in claim 22, wherein the integral forming is carried out in an injection moulding tool.
30. A mould for a respiratory mask for administering a breathable gas to a patient, the respiratory mask comprising a first component formed from an elastomeric material; and a second component formed from a material that is less flexible than the elastomeric material, wherein the first component is integrally formed onto the second component, wherein the mould comprises a mould cavity in which the first component is moulded onto the second component.
31. A mould as claimed in claim 30, wherein the mould cavity has a first portion with a shape that substantially matches the shape of the first component and a second portion with a shape that substantially matches the shape of the second component.
32. A mould as claimed in claim 30, wherein the integral forming is such that the first component can be manually separated from the second component.
33. A mould as claimed in claim 30, wherein the integral forming is such that the first component is joined to the second component in an intimately adhering manner.

34. A mould as claimed in claim 30, wherein the integral forming is carried out in an injection moulding tool.
35. A respiratory mask comprising:
a substrate made of a relatively rigid material, wherein the substrate includes at least one treated portion inclined to accept a reactive substance; and
an elastomer that is made of a relatively more flexible material compared to the relatively rigid material of the substrate, said elastomer being applied to the substrate and secured to the substrate via an induced adhesive bond formed between said treated portion and a surface of the elastomer abutting the treated portion.
36. The respiratory mask according to claim 35, wherein the mask includes a mask frame and an elbow provided to the frame, wherein the elbow includes at least one selected portion including said substrate and said elastomer is provided to the selected portion.
37. The respiratory mask according to claim 36, wherein the elbow includes a plurality of components and the selected portion includes the interface between any two elbow components.
38. The respiratory mask according to claim 35, wherein the mask includes a mask frame and an elbow provided to the frame, wherein the frame includes a socket defining said substrate and the elastomer is provided to said socket.
39. The respiratory mask according to claim 35, wherein the mask includes a mask frame, a cushion provided to the frame and a forehead support positioned above the frame.

40. The respiratory mask according to claim 39, further comprising a flexible portion coupling the frame and the forehead support, the flexible portion including a structural spine including said substrate and at least one disc including said elastomer.
41. The respiratory mask according to claim 39, further comprising a flexible portion coupling the frame and the forehead support, the flexible portion including an exoskeleton including said substrate and a tube including said elastomer.
42. The respiratory mask according to claim 41, wherein the tube has first and second ends that are co-moulded to the frame and the forehead support, respectively.
43. The respiratory mask according to claim 36, wherein the elastomer is in the form of a seal.
44. The respiratory mask according to claim 43, wherein the seal includes a relatively long elastomer lip flexibly positionable and bendable against and adjacent a socket of the frame, and at least one relatively shorter lip positioned between the relatively long elastomer lip and an outer circumference of the elbow in use.
45. The respiratory mask according to claim 43, wherein the seal includes at least one relatively shorter lip extending radially between the elbow and the socket of the frame.
46. The respiratory mask according to any one of claims 44-45, wherein the at least one relatively shorter lip includes two lips.
47. The respiratory mask according to any one of claims 43-46, wherein the elbow includes a first circumferential flange provided towards a proximal portion of the elbow and a second circumferential flange provided towards a distal portion of the elbow,

wherein the seal is provided on the outer circumference of the elbow between the first and second flanges.

48. The respiratory mask according to claim 47, further comprising a third circumferential flange between the first and second flanges, the seal being provided between the first and third flanges.

49. The respiratory mask according to any one of claims 47-48, wherein the second flange includes a surface to engage an inboard surface of the socket of the frame.

50. The respiratory mask according to any one of claims 48-49, wherein the third flange includes a surface that engages with a shoulder of the elbow.

51. The respiratory mask according to any one of claims 48-50, further comprising a fourth circumferential flange adjacent the third flange, wherein the seal is provided between the third and fourth flanges.

52. The respiratory mask according to any one of claims 43, 47-51, wherein the seal includes a radial seal portion, an axial seal portion and an external seal portion.

53. The respiratory mask according to any one of claims 43, 47-51 wherein the seal includes a radial lip seal that seals against an inner surface of a socket of the elbow and an axial lip seal that seals against an end face of the socket.

54. The respiratory mask according to claim 35, wherein the mask includes a mask frame made at least in part from said elastomer and a retaining ring provided to the frame, wherein the retaining ring includes at least a selected portion including said substrate.

55. The respiratory mask according to claim 35, further comprising a headgear assembly, wherein the headgear assembly includes a yoke associated with a strap and a seal ring provided to the yoke, wherein the yoke includes at least one selected portion including the substrate and the elastomer forms at least a part of the seal ring.
56. The respiratory mask according to claim 39, wherein the mask includes a frame and a gas washout vent having at least one hole or pore, wherein the frame includes at least one selected portion including the substrate and the gas washout vent is formed at least in part from said elastomer.
57. The respiratory mask according to claim 35, wherein the mask includes a frame having an aperture and a plug provided to close the aperture, the frame including at least a selected portion including said substrate and the plug is formed at least in part from said elastomer.
58. The respiratory mask according to claim 35, wherein the mask includes a conduit including said substrate and a wall member formed at least in part by said elastomer, said substrate including a reinforcement structure.
59. The respiratory mask according to claim 58, wherein said reinforcement structure includes a helical member.
60. The respiratory mask according to claim 58, wherein said reinforcement structure includes at least two circular ribs interconnected by longitudinal members provided on alternating opposing sides of the wall member.
61. The respiratory mask according to claim 58, wherein the reinforcement structure includes a plurality of circular ribs interconnected by dual longitudinal members provided on opposing sides of the wall member.

62. The respiratory mask according to claim 35, wherein the frame includes a port portion and a port cap provided to the frame, wherein the port portion includes at least a selected portion including the substrate and the port cap is formed at least in part with said elastomer.

63. The respiratory mask according to claim 35, wherein said mask includes a frame and an elbow provided to the frame, wherein said substrate with said treated portion is formed on an exterior surface of said frame and/or said elbow, and said elastomer is provided to each said treated portion to create a gripping portion and/or a logo.

64. The respiratory mask according to claim 35, wherein said mask includes a frame with said treated portion and a bladder provided to the frame and formed at least in part from said elastomer.

65. The respiratory mask according to claim 35, wherein the mask includes a frame including at least one port, and nasal cannulae, wherein the frame includes said treated portion of the substrate and the cannulae are formed at least in part from the elastomer, the cannulae being in communication with the port.

66. The respiratory mask according to claim 35, wherein the mask includes a frame, an elbow provided to the frame, and a seal made at least in part from the elastomer, wherein said substrate is provided as part of said elbow or said frame.

67. The respiratory mask according to claim 66, wherein the seal is formed on the elbow.

68. The respiratory mask according to claim 67, wherein the seal is formed on an inner circumferential portion of the elbow to seal against a base portion of the frame inlet.

69. The respiratory mask according to claim 67, wherein the seal is formed on an outer circumferential portion of the elbow to seal against the frame.
70. The respiratory mask according to claim 68, wherein the seal is formed on the frame.
71. The respiratory mask according to claim 66, wherein the seal is a syringe type seal.
72. The respiratory mask according to claim 66, wherein the seal is a blade style seal.
73. The respiratory mask according to claim 66, wherein the seal is an axial type seal structured to engage an angled face of the frame.
74. The respiratory mask according to claim 66, wherein the seal has a generally rectangular cross-section.
75. The respiratory mask according to claim 35, further comprising a forehead pad provided to a forehead support, the forehead pad being co-moulded to the forehead support and secured thereto without adhesion.
76. The respiratory mask according to claim 35, wherein the mask includes a mask frame including the substrate and a mask cushion including the elastomer.
77. The respiratory mask according to claim 76, wherein the frame includes a peripheral region and the cushion includes a T-shaped or L-shaped rim applied to the treated portion of the frame.

78. The respiratory mask according to claim 76, wherein the treated portion forms at least a portion of a diagonal joint, a lap joint and/or a V-joint.

79. The respiratory mask according to claim 76, wherein the cushion includes an expandable bladder having an interior defined by an interior surface of the elastomer and a portion of the frame that is not treated, and the frame includes a port to allow introduction of a substance delivered to the interior to expand the bladder.

80. The respiratory mask according to claim 79, wherein the substance includes gel, foam, and/or liquid.

81. The respiratory mask according to claim 35, wherein the mask includes a mask frame a cushion and a cushion clip to secure the cushion to the frame, wherein the substrate is provided as part of the cushion clip and the cushion includes the elastomer.

82. The respiratory mask according to any one of claims 35-81, wherein the treated portion includes a plasma treated surface.

83. The respiratory mask according to claim 82, wherein the plasma treated surface is an atmospheric gas plasma treated surface.

84. The respiratory mask according to any one of claims 35-81, wherein the selected portion includes a corona treated surface.

85. The respiratory mask according to any one of claims 35-81, wherein the selected portion includes at least one surface treated with an adhesion promoter or solvent.

86. The respiratory mask according to any one of claims 35-81, wherein the selected portion includes a flame oxidized surface.

87. The respiratory mask according to any one of claims 35-81, wherein the adhesive bond includes an adsorptive bond, a chemical bond, a diffusion bond, and/or an electrostatic bond.
88. The respiratory mask according to claim 35, wherein the relatively rigid material includes polycarbonate, polypropylene, polysulphone, phenol formaldehyde, thermoplastic or thermoset polymer..
89. The respiratory mask according to any one of claims 35-88, wherein the relatively more flexible material includes liquid silicone rubber, solid silicone rubber and/or thermoplastic elastomers.
90. The respiratory mask according to claim 35, wherein the treated portion of the substrate and the surface of the elastomer are overmoulded.
91. The respiratory mask according to claim 90, wherein the selected portion of the substrate and the surface of the elastomer component are co-moulded.
92. The respiratory mask according to any one of claims 35-91, wherein the elastomer is a non-self adhesive elastomer.
93. The respiratory mask according to any one of claims 35-92, wherein portions of said elastomer in contact with the treated portion are subject to said adhesive bond while portions not in contact with said treated portion are not strongly bonded to the substrate.
94. The respiratory mask according to claim 93, wherein said treated portion is only a sub-portion of said substrate.

95. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate,
wherein the mask includes a mask frame and an elbow provided to the frame, and
wherein the elbow or frame includes at least one selected portion including said substrate,
and the method further comprises overmoulding said elastomer onto the selected portion.
96. The method according to claim 95, wherein said substrate is formed on one or
more exterior surface portions of said frame and/or said elbow, and said elastomer is
provided to each said exterior surface portion to create a gripping portion and/or a logo.
97. The method according to any one of claims 95-96, wherein the elastomer is in the
form of a seal formed on the elbow and/or frame.
98. The method according to claim 97, wherein the seal is formed on an inner
circumferential portion of the elbow to seal against a base portion of an inlet of the frame.
99. The method according to claim 97, wherein the seal is formed on an outer
circumferential portion of the elbow to seal against the frame.
100. The method according to any one of claims 97-99, wherein the seal is a syringe
type seal.
101. The method according to any one of claims 97-99, wherein the seal is a blade
style seal.
102. The method according to any one of claims 97-99, wherein the seal is an axial
type seal structured to engage an angled face of the frame.

103. The method according to any one of claims 97-99, wherein the seal has a generally rectangular cross-section.
104. The method according to claim 97, wherein the seal includes a relatively long elastomer lip flexibly positionable and bendable against and adjacent a socket of the frame, and at least one relatively shorter lip positioned between the relatively long elastomer lip and an outer circumference of the elbow in use.
105. The method according to claim 97, wherein the seal includes at least one relatively shorter lip extending radially between the elbow and the socket of the frame.
106. The method according to any one of claims 104-105, wherein the at least one relatively shorter lip includes two lips.
107. The method according to any one of claims 94, 104-106, wherein the elbow includes a first circumferential flange provided towards a proximal portion of the elbow and a second circumferential flange provided towards a distal portion of the elbow, wherein the seal is provided on the outer circumference of the elbow between the first and second flanges.
108. The method according to claim 107, further comprising a third circumferential flange between the first and second flanges, the seal being provided between the first and third flanges.
109. The method according to any one of claims 107-108, wherein the second flange includes a surface to engage an inboard surface of the socket of the frame.
110. The method according to any one of claims 108-109, wherein the third flange includes a surface that engages with a shoulder of the elbow.

111. The method according to any one of claims 108-110, further comprising a fourth circumferential flange adjacent the third flange, wherein the seal is provided between the third and fourth flanges.
112. The method according to any one of claims 97, 107-111, wherein the seal includes a radial seal portion, an axial seal portion and an external seal portion.
113. The method according to any one of claims 97, 107-111 wherein the seal includes a radial lip seal that seals against an inner surface of a socket of the elbow and an axial lip seal that seals against an end face of the socket.
114. The method according to claim 95, wherein the elbow includes a plurality of components and the selected portion includes the interface between any two elbow components.
115. The method according to claim 95, wherein the frame includes a socket defining said substrate and the elastomer is provided to said socket.
116. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame, a cushion provided to the frame and a forehead support positioned above the frame, wherein the mask comprises a flexible portion coupling the frame and the forehead support, the flexible portion including a structural member including said substrate and at least one disc or tube including said elastomer.
117. The method according to claim 116, wherein the tube has first and second ends that are co-moulded to the frame and the forehead support, respectively.

118. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame made at least in part from said elastomer and a retaining ring including said substrate, wherein the method further includes overmoulding the frame onto the ring.
119. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask comprises a frame and a cushion and a headgear assembly to support the frame and cushion, wherein the headgear assembly includes a yoke associated with a strap and a seal ring provided to the yoke, wherein the yoke includes at least one selected portion including the substrate and the method comprises overmoulding the seal ring onto the yoke.
120. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a frame and a gas washout vent having at least one hole or pore, wherein the frame includes at least one selected portion including the substrate and the method comprises co-moulding the gas washout vent onto the frame.
121. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a frame having an aperture and a plug provided to close the aperture, the frame including at least a selected portion including said substrate and the method comprise overmoulding the plug onto the frame.

122. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a conduit including said substrate and a wall member formed at least in part by said elastomer, and said method further comprises overmoulding the wall member and the reinforcement member.
123. The method according to claim 122, wherein said reinforcement structure includes a helical member.
124. The method according to claim 122, wherein said reinforcement structure includes at least two circular ribs interconnected by longitudinal members provided on alternating opposing sides of the member wall.
125. The method according to claim 122, wherein the reinforcement structure includes a plurality of circular ribs interconnected by dual longitudinal members provided on opposing sides of the member wall.
126. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the frame includes a port portion and a port cap provided to the frame, wherein the port portion includes at least a selected portion including the substrate and the method further comprises overmoulding the port cap onto the frame.
127. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and

overmoulding an elastomer to or with the substrate, wherein said mask includes a frame with said substrate and a bladder is provided to the frame and formed at least in part from said elastomer.

128. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a frame including at least one port, and nasal cannulae, wherein the frame includes said substrate and the cannulae are formed at least in part from the elastomer, the cannulae being in communication with the port.
129. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a frame, a cushion, a forehead support positioned above the frame, and a forehead pad provided to the forehead support, the forehead pad including said elastomer and the forehead support including said substrate.
130. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame including the substrate and a mask cushion including the elastomer, wherein the frame includes a peripheral region and the cushion includes a T-shaped or L-shaped rim overmoulded to the frame.
131. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame including the substrate and a mask cushion including the elastomer, in which

the mask frame and the mask cushion form at least one of a diagonal joint, a lap joint and/or a V-joint.

132. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a frame and a cushion, the cushion having an expandable bladder having an interior defined by an interior surface of the elastomer and a portion of the frame that is not treated, and the frame includes a port to allow introduction of a substance delivered to the interior to expand the bladder.
133. The method according to claim 132, wherein the substance includes gel, foam, and/or liquid.
134. A method for manufacturing a respiratory mask comprising:
forming a substrate made of a relatively rigid material; and
overmoulding an elastomer to or with the substrate, wherein the mask includes a mask frame a cushion and a cushion clip to secure the cushion to the frame, wherein the substrate is provided as part of the cushion clip and the cushion includes the elastomer.
135. The method according to any one of claims 95-134, wherein the overmoulding includes selectively treating the substrate with plasma.
136. The method according to claim 135, wherein the plasma is an atmospheric gas plasma.
137. The method according to any one of claims 95-134, wherein the overmoulding includes one or more of the following: corona treatment, co-injection moulding, moving cores moulding, rotating platen and/or stripper plate moulding.

138. The method according to any one of claims 95-134, wherein the overmoulding includes treating at least one surface with an adhesion promoter or solvent.
139. The method according to any one of claims 95-134, wherein the overmoulding includes treating at least one surface of the substrate with flame oxidation.
140. The method according to any one of claims 95-134, further comprising bonding the substrate and the elastomer to form an adhesive bond including at least one of an adsorptive bond, a chemical bond, a diffusion bond, and/or an electrostatic bond.
141. The method according to any one of claims 95-140, wherein the relatively rigid material includes polycarbonate, polypropylene, polysulphone, phenol formaldehyde, thermoplastic or thermoset polymer.
142. The method according to any one of claims 95-141, wherein the elastomer includes liquid silicone rubber, solid silicone rubber and/or thermoplastic elastomers.
143. The method according to claim 95, wherein the selected portion of the substrate and the surface of the elastomer component are co-moulded.
144. The method according to any one of claims 95-141, wherein the elastomer is a non-self adhesive elastomer.
145. The method according to any one of claims 95-143, wherein portions of said elastomer in contact with the selected portion are subject to said adhesive bond while portions not in contact with said treated portion are not bonded to the substrate.

146. The method according to claim 95, wherein said selected portion is only a sub-portion of said substrate.

147. A humidifier tub for a flow generator comprising:

a substrate made of a relatively rigid material, wherein the substrate includes at least one treated portion inclined to accept a reactive substance; and

an elastomer that is made of a relatively more flexible material compared to the relatively rigid material of the substrate, said elastomer being applied to the substrate and secured to the substrate via an induced adhesive bond formed between said treated portion and a surface of the elastomer abutting the treated portion

wherein the humidifier tub includes a lid having said substrate and a seal made in part from said elastomer.

148. A method for manufacturing a humidifier tub comprising:

forming a substrate made of a relatively rigid material; and

overmoulding an elastomer to or with the substrate, wherein the humidifier tub includes a lid having said substrate and a seal made in part from said elastomer.

149. A humidifier tub comprising:

a substrate made of a relatively rigid material; and

an elastomer overmoulded with or to the substrate, wherein the humidifier tub includes a lid having said substrate and a seal made in part from said elastomer.

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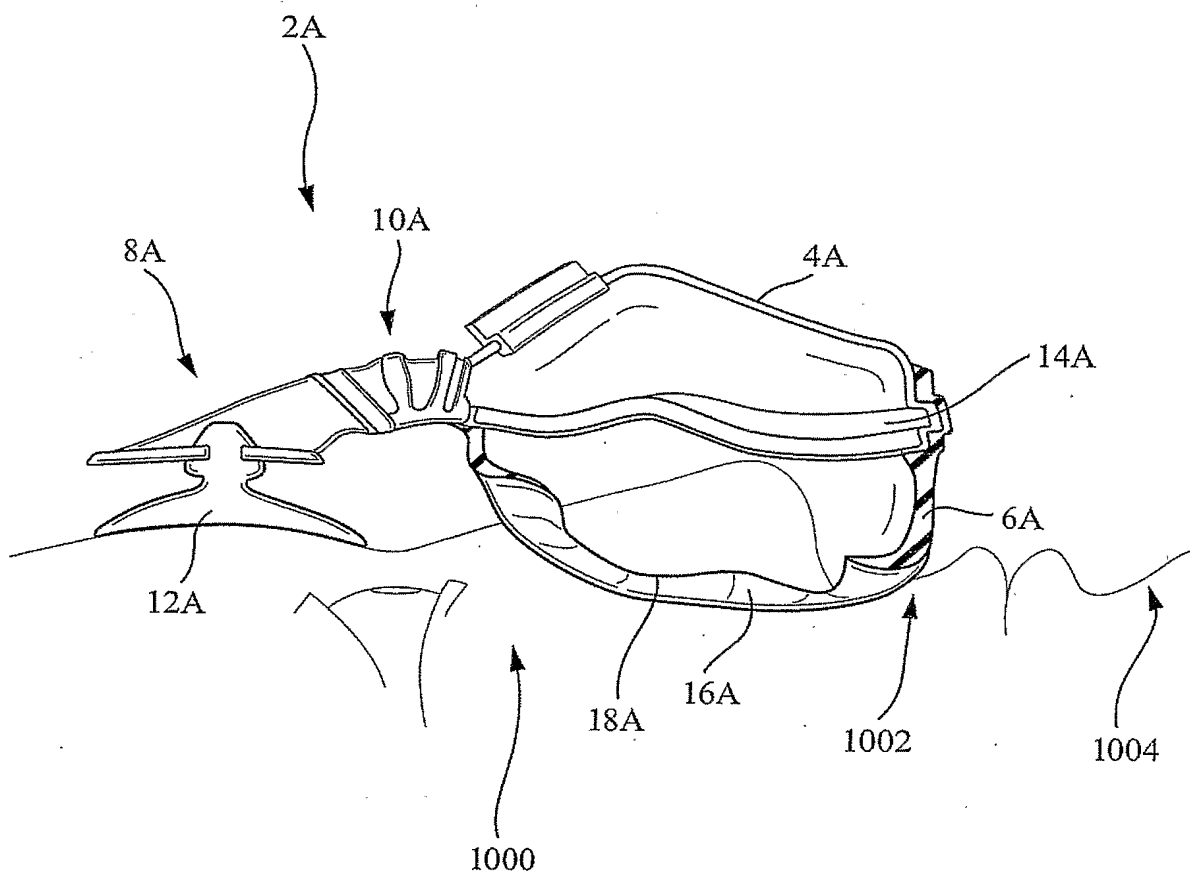


FIG. 1

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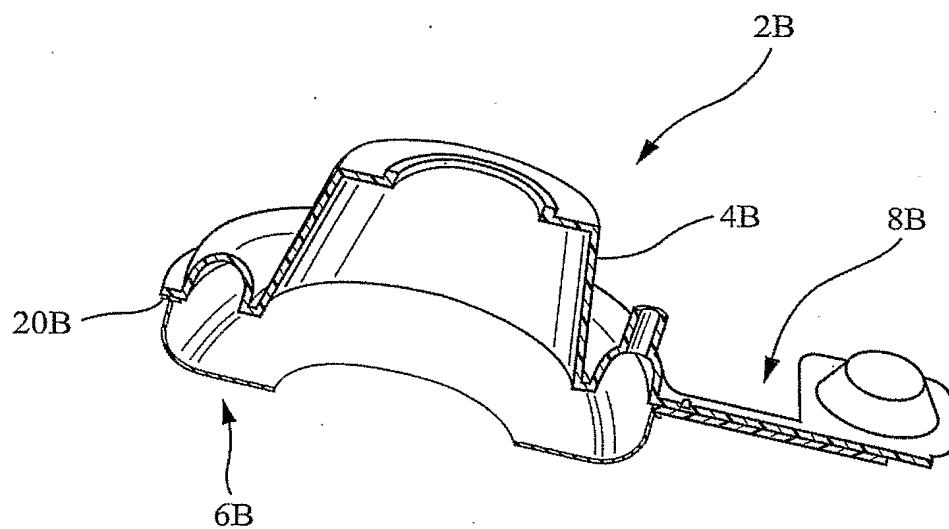


FIG. 2

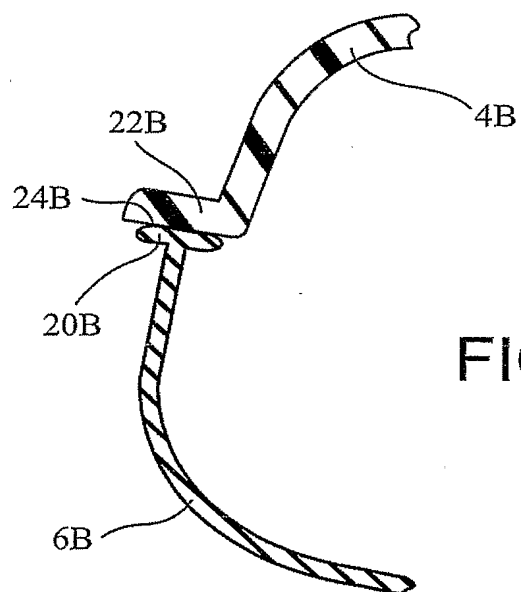


FIG. 3

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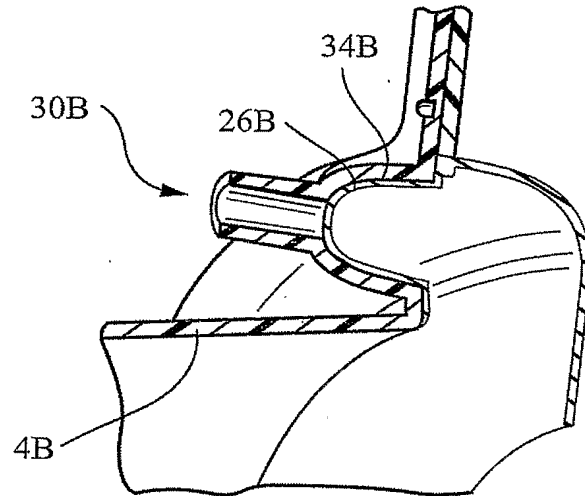


FIG. 4

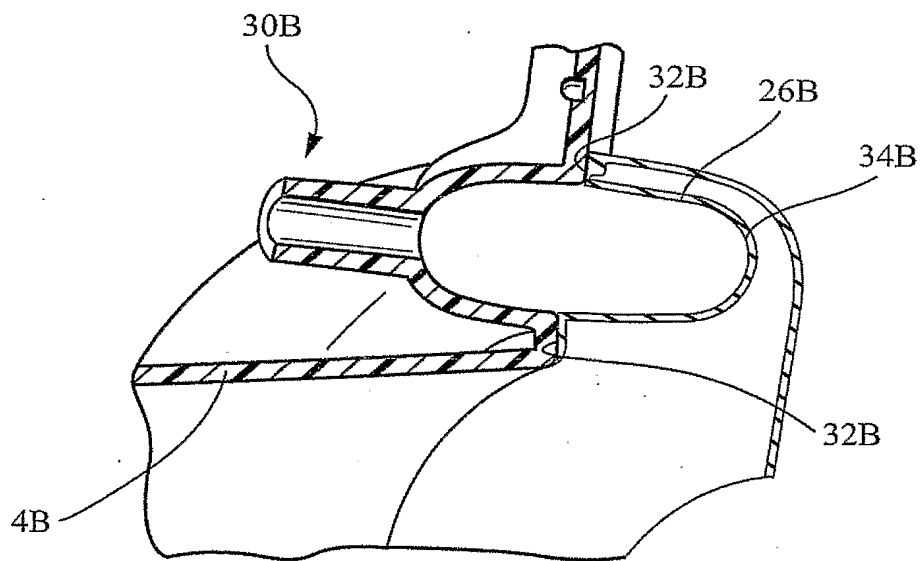


FIG. 5

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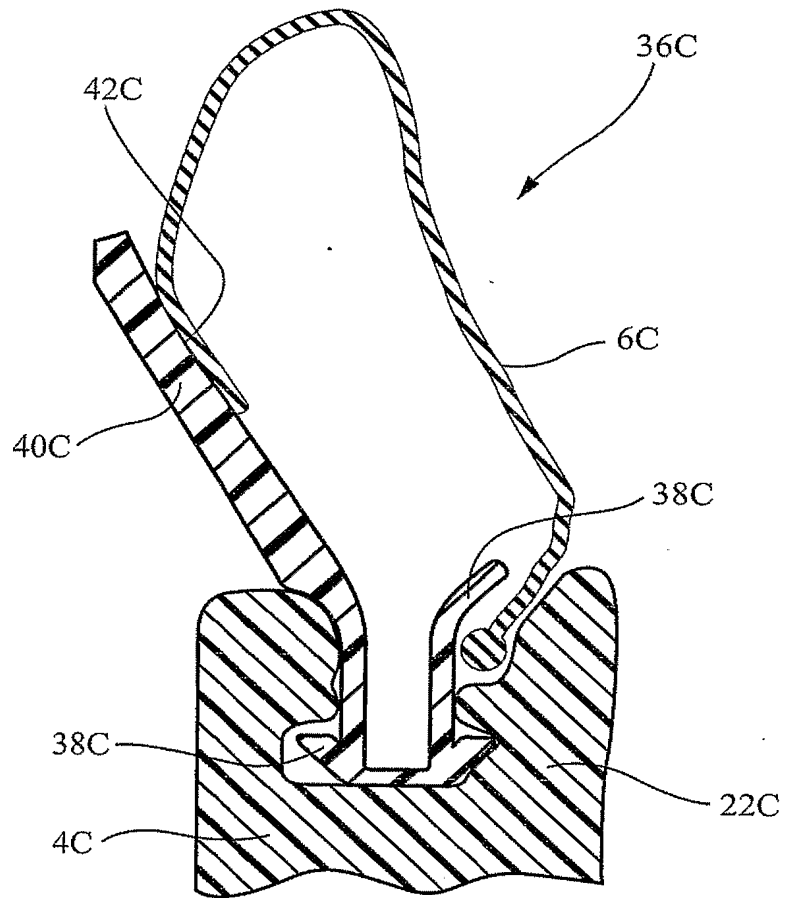
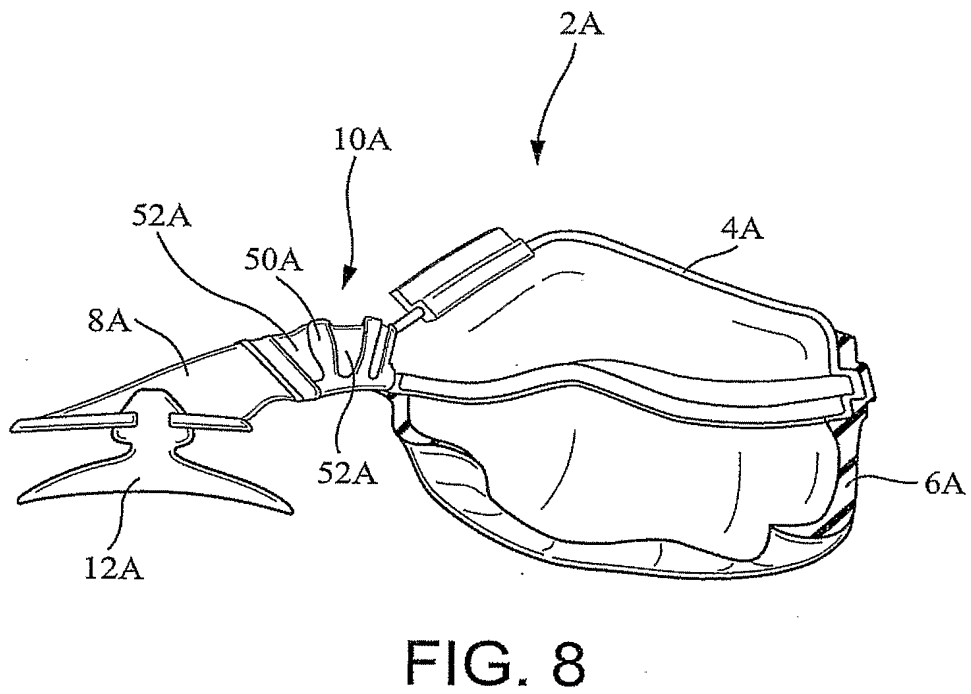
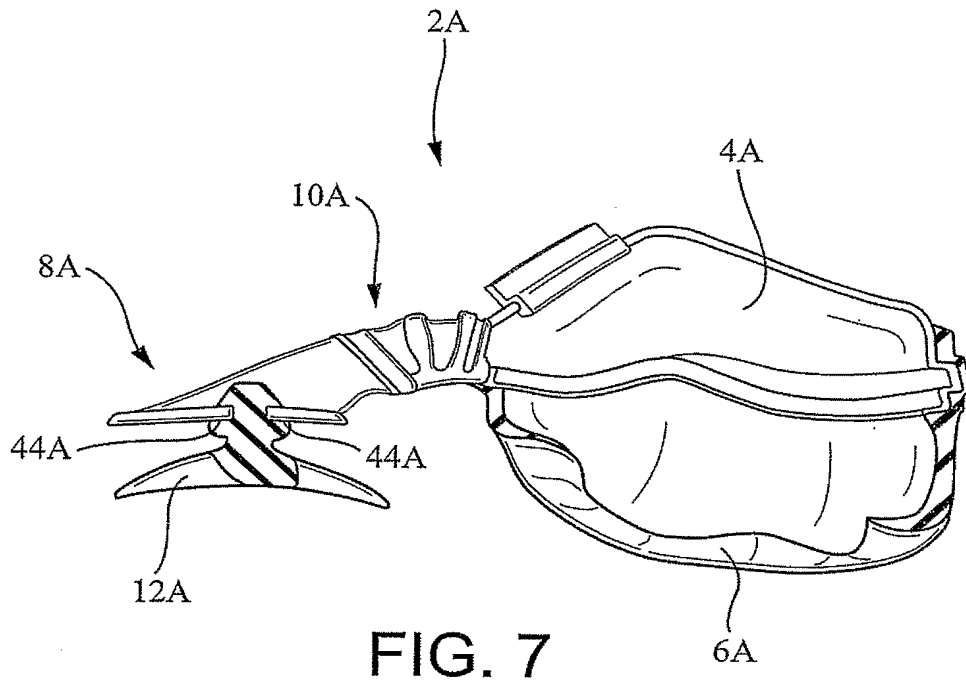


FIG. 6

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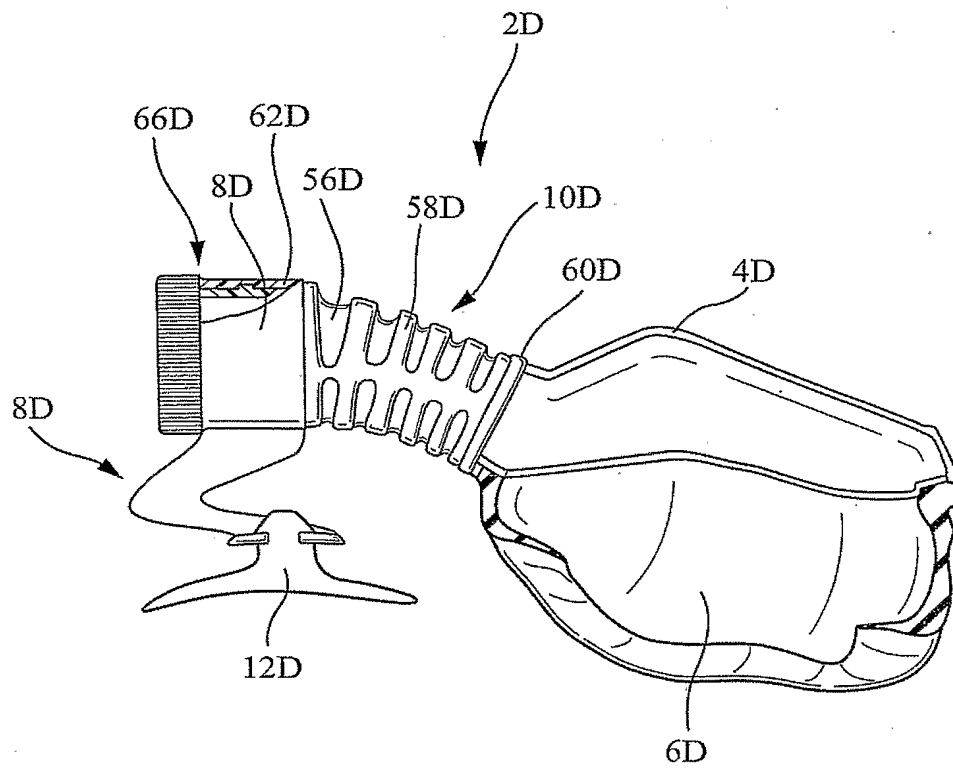


FIG. 9

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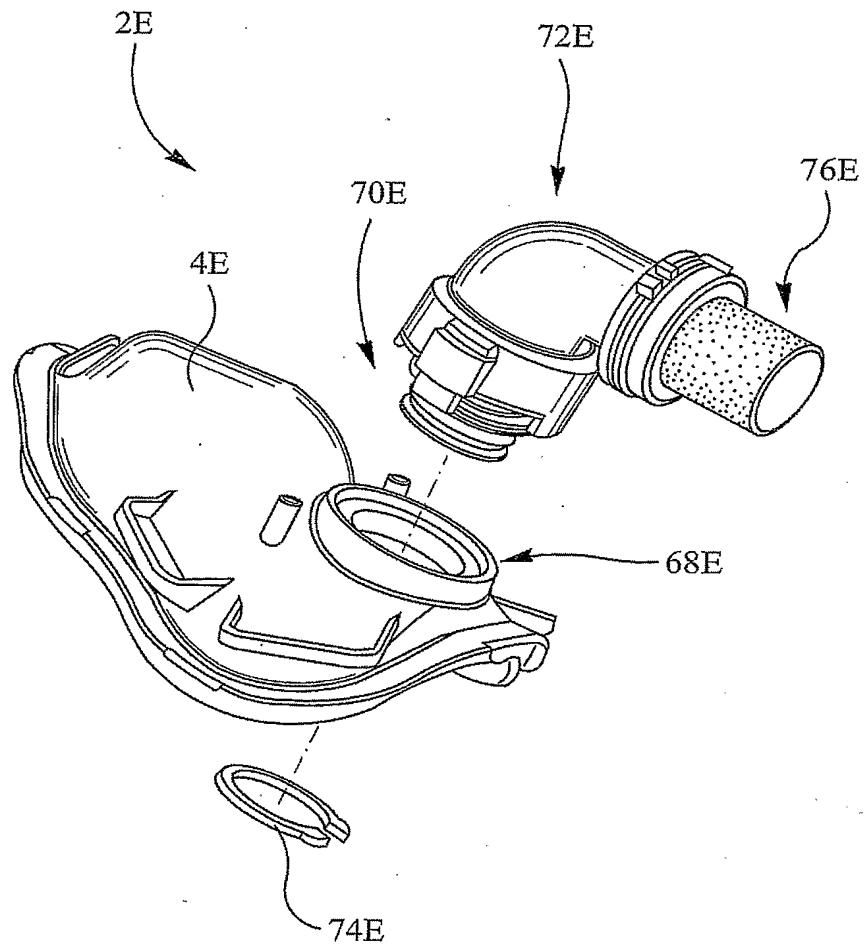


FIG. 10

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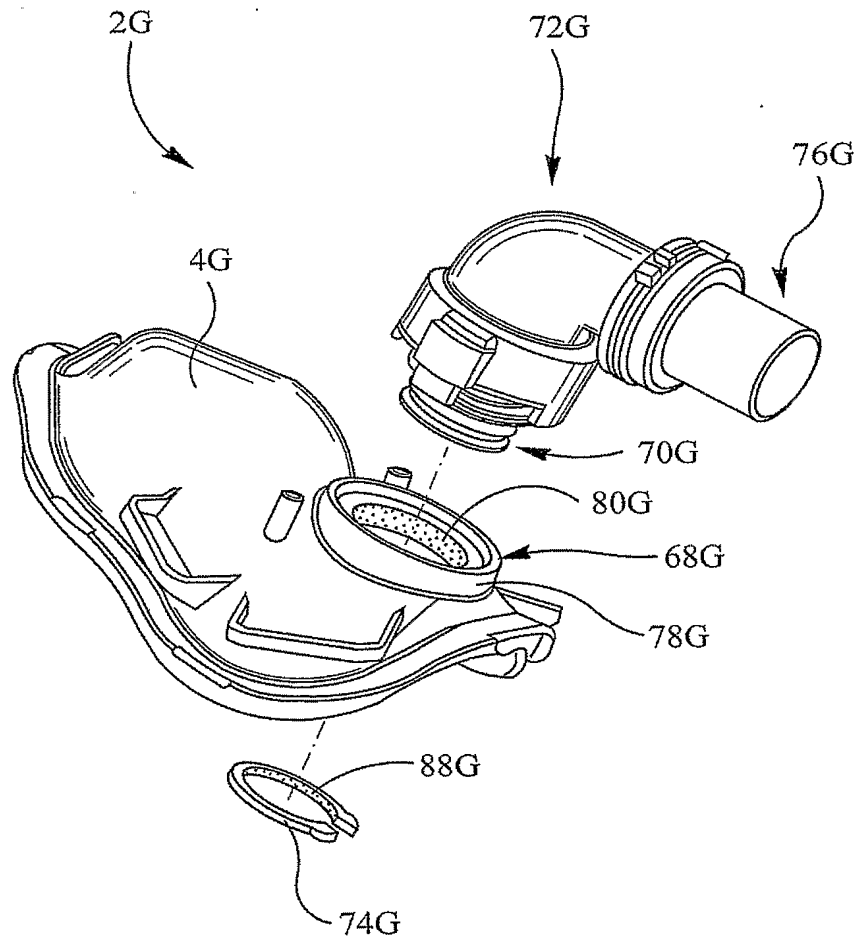


FIG. 11

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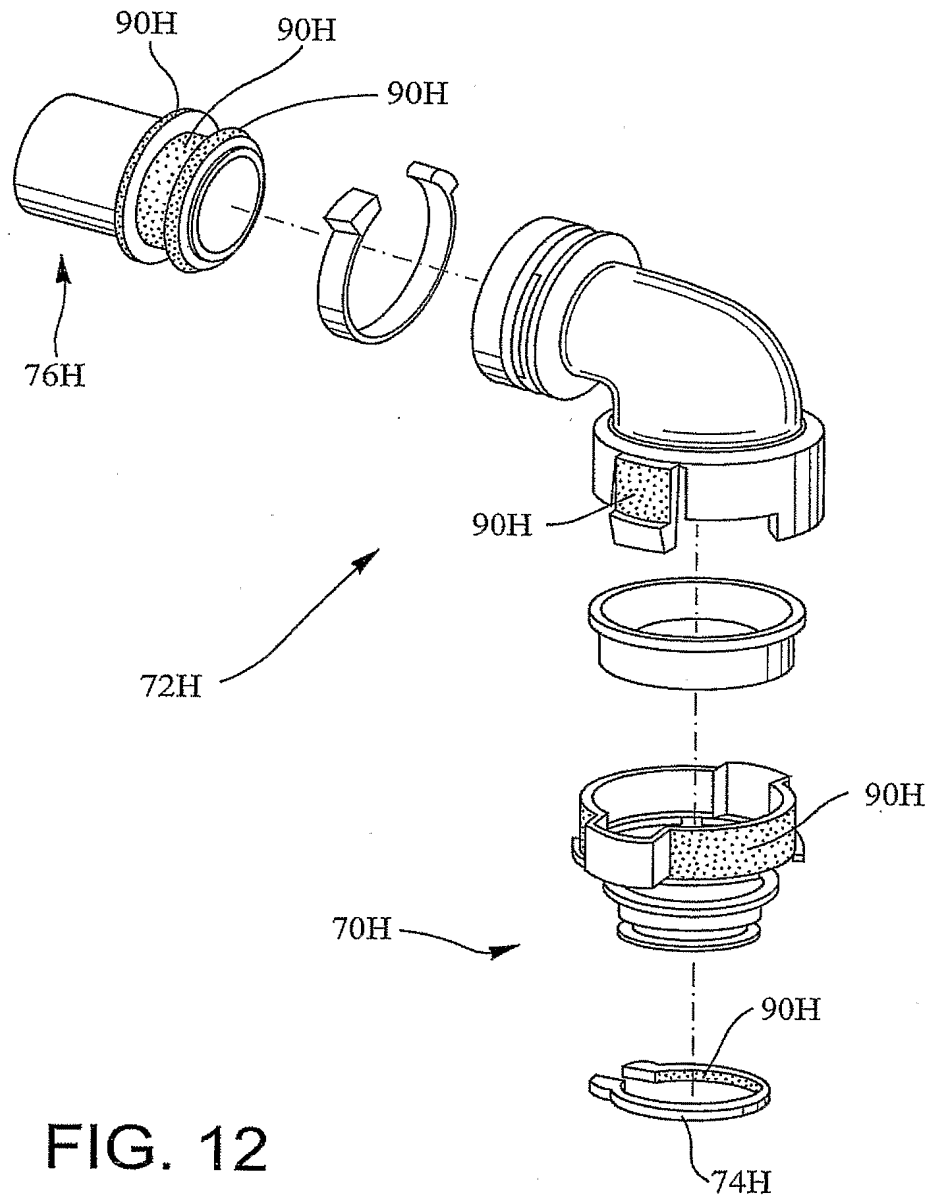


FIG. 12

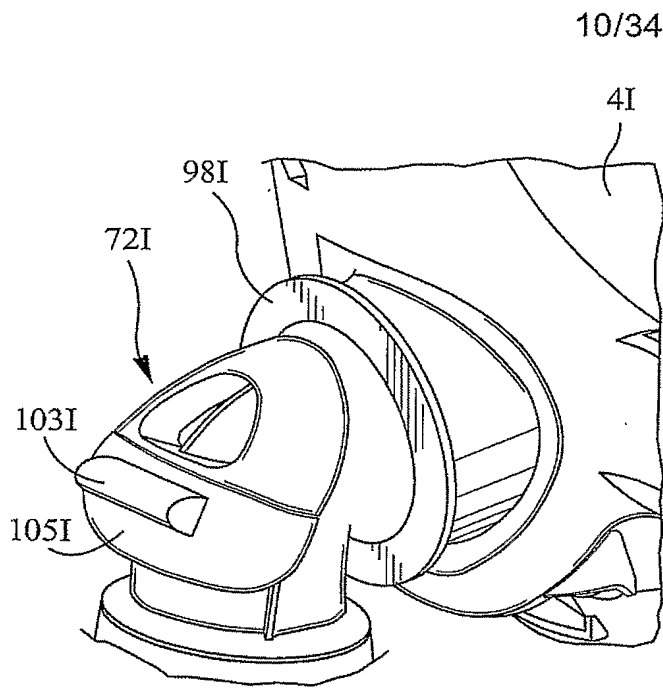


FIG. 13

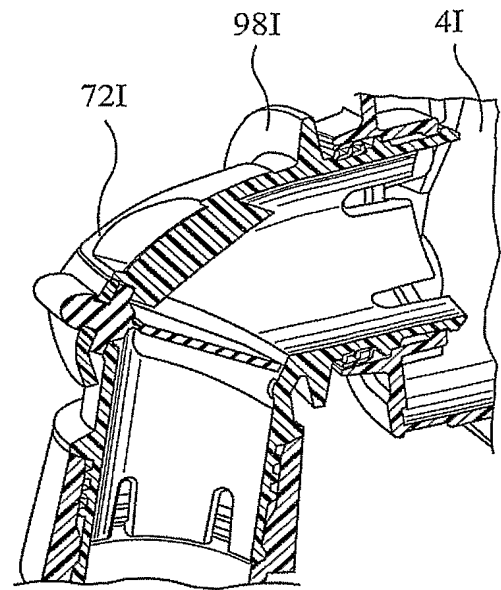


FIG. 14

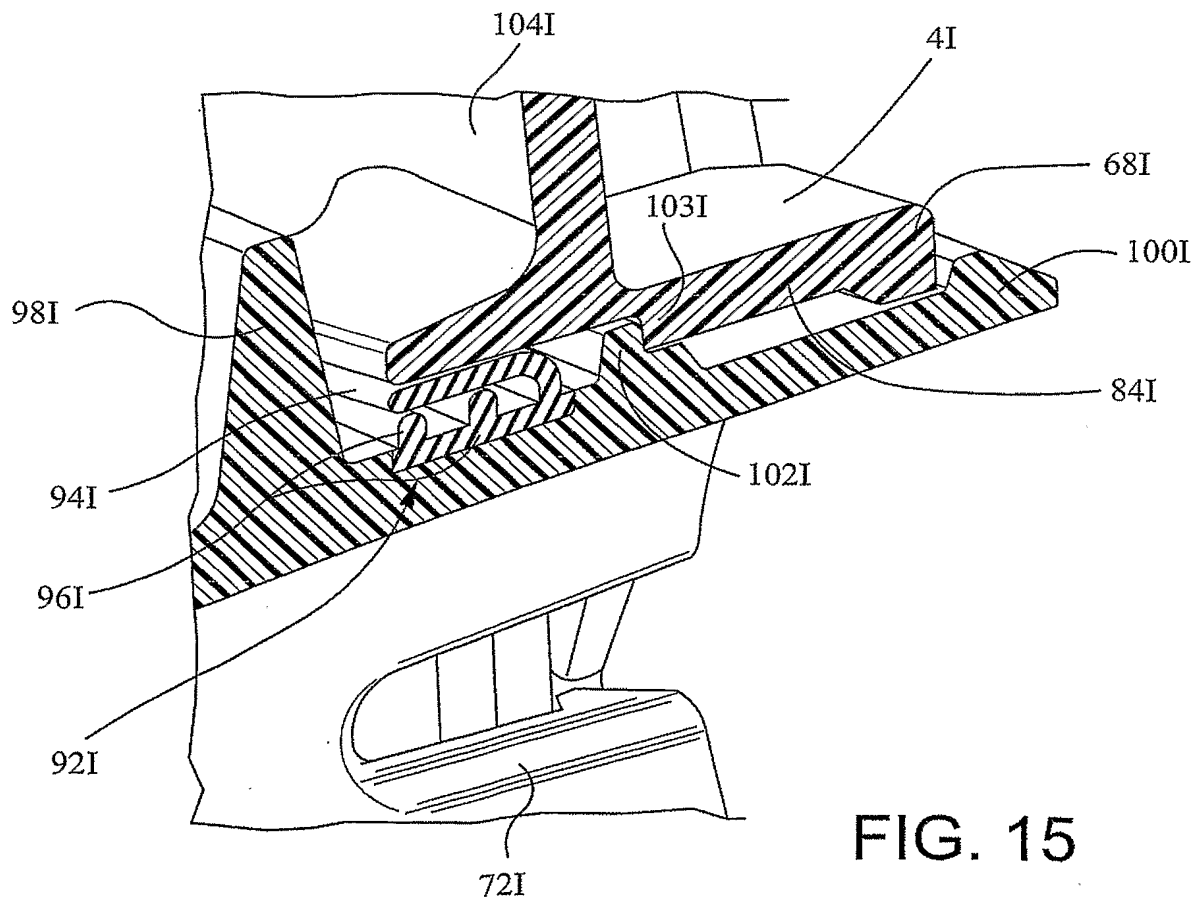


FIG. 15

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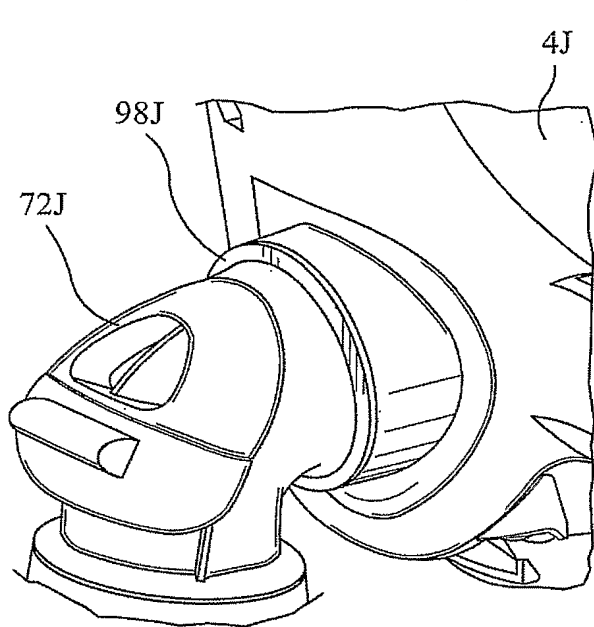


FIG. 16

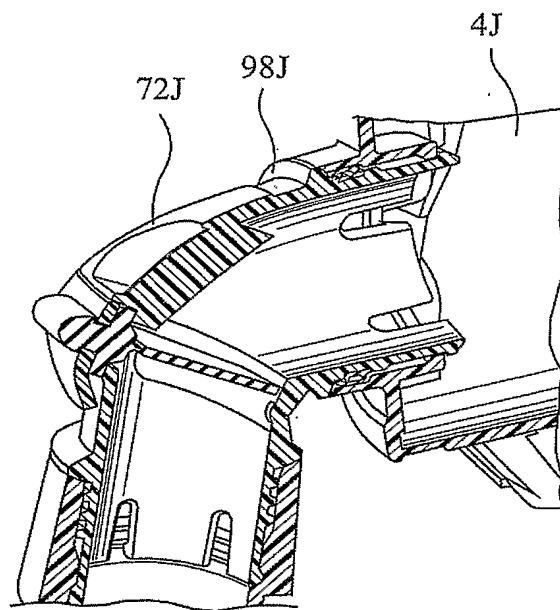


FIG. 17

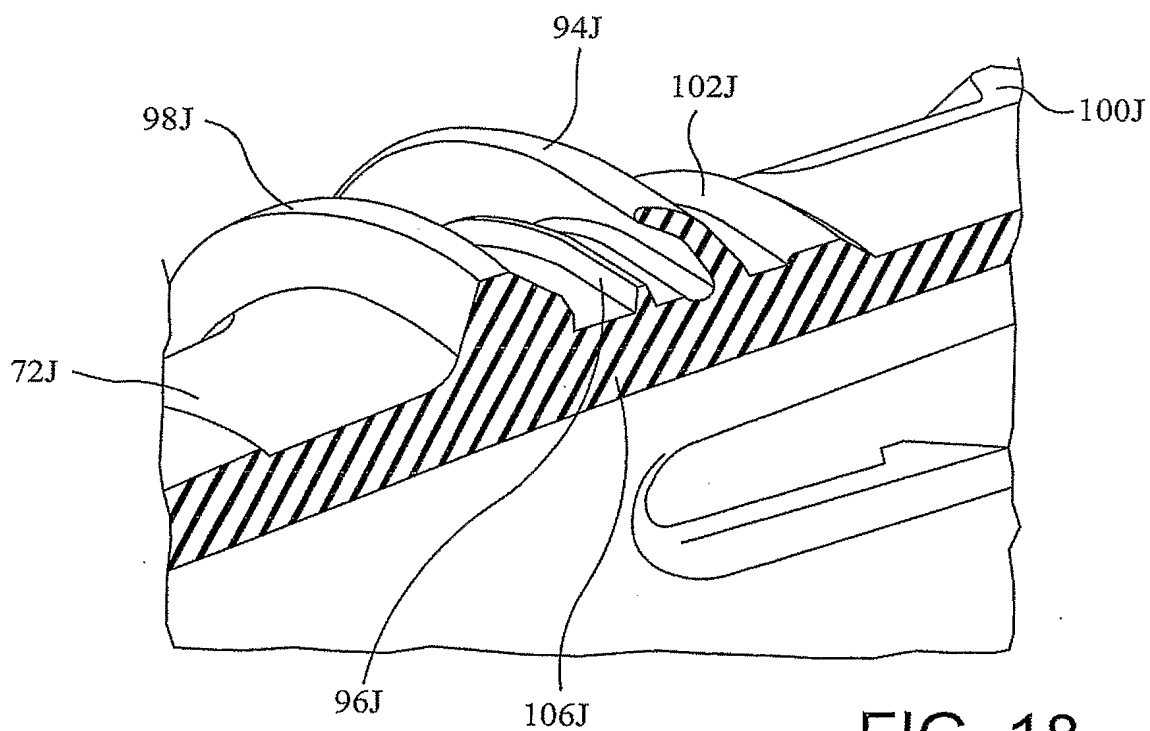


FIG. 18

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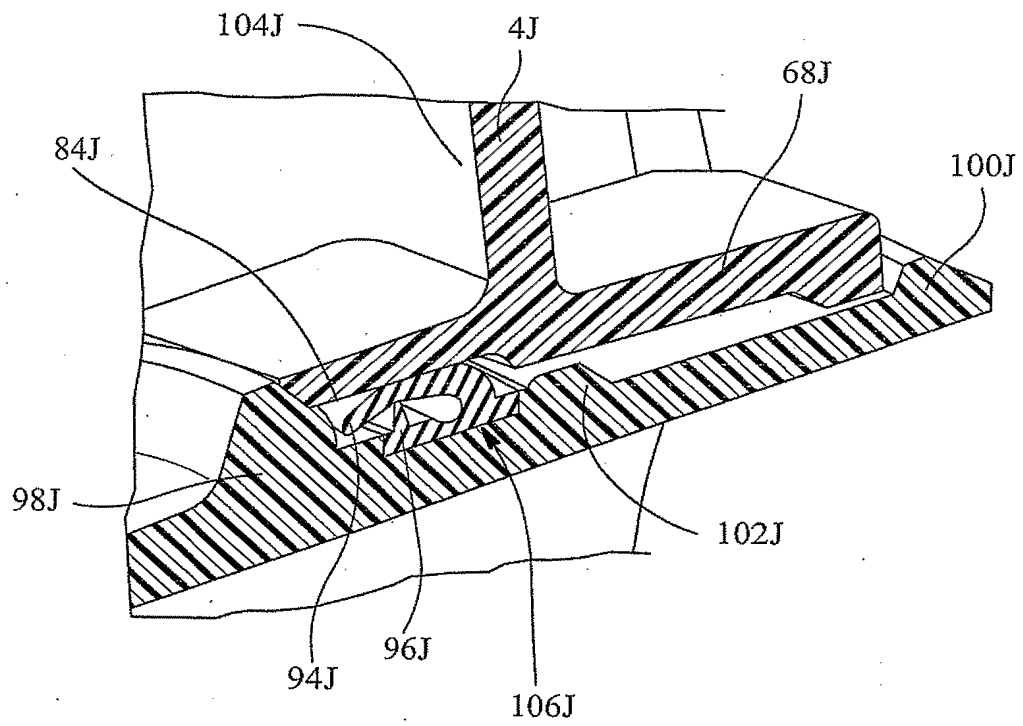


FIG. 19

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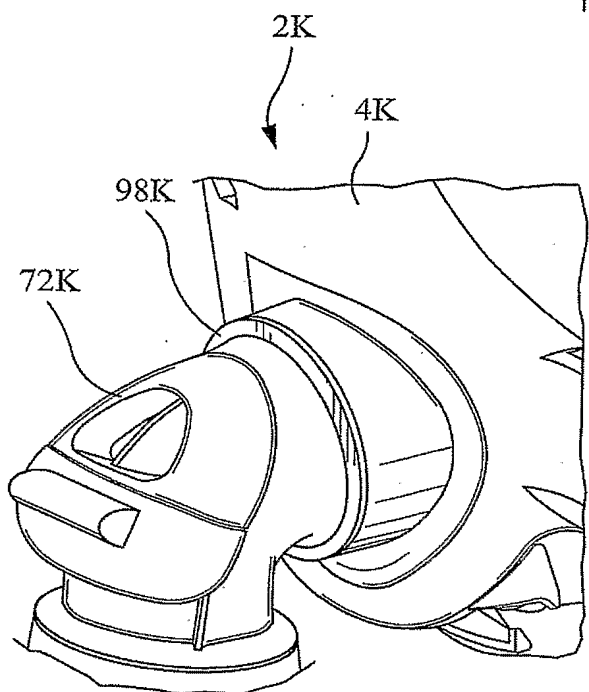


FIG. 20

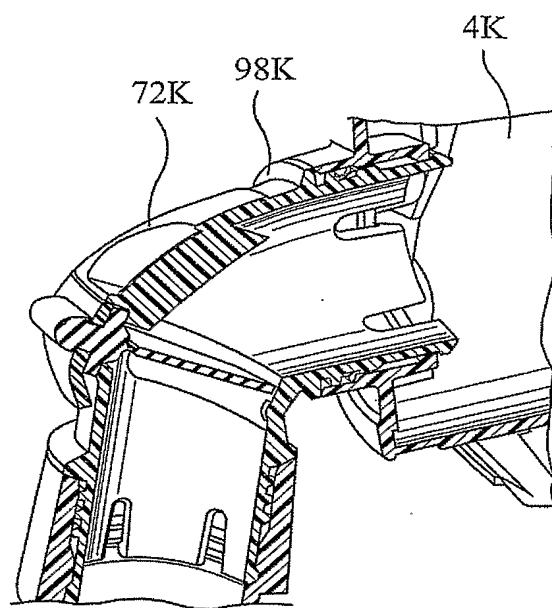


FIG. 21

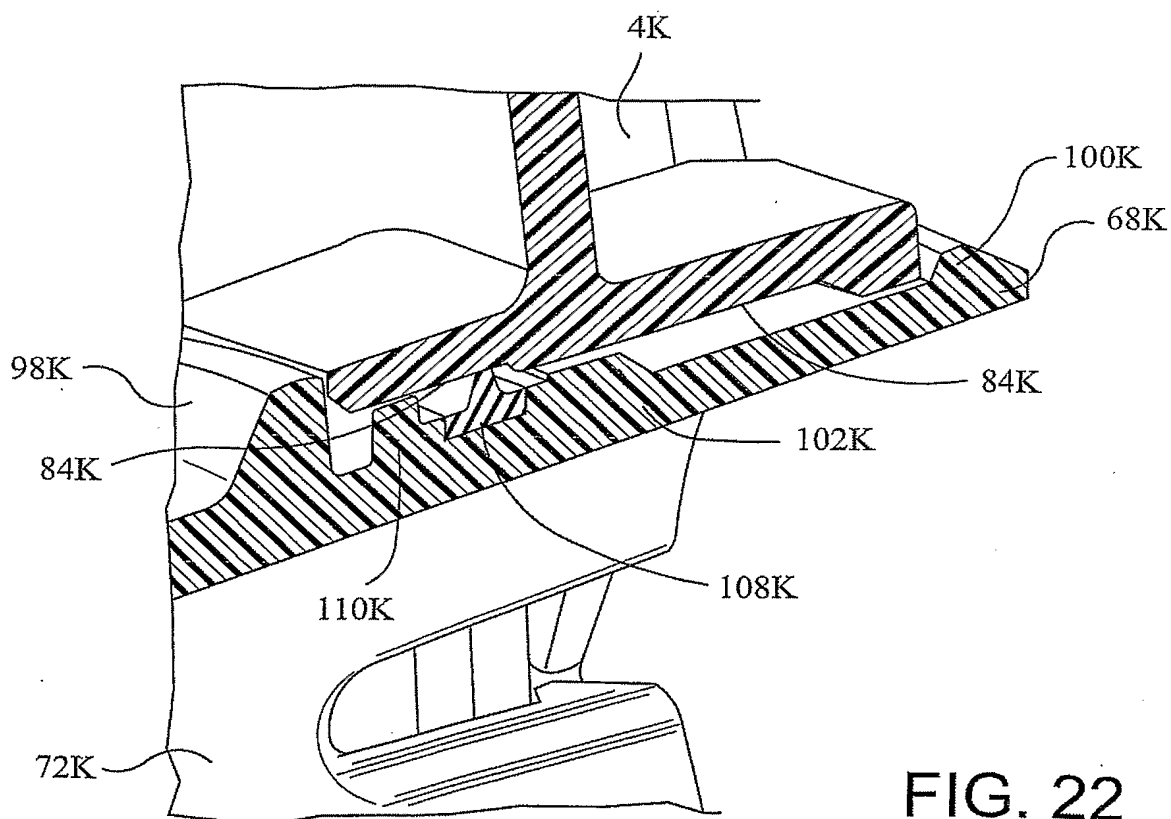


FIG. 22

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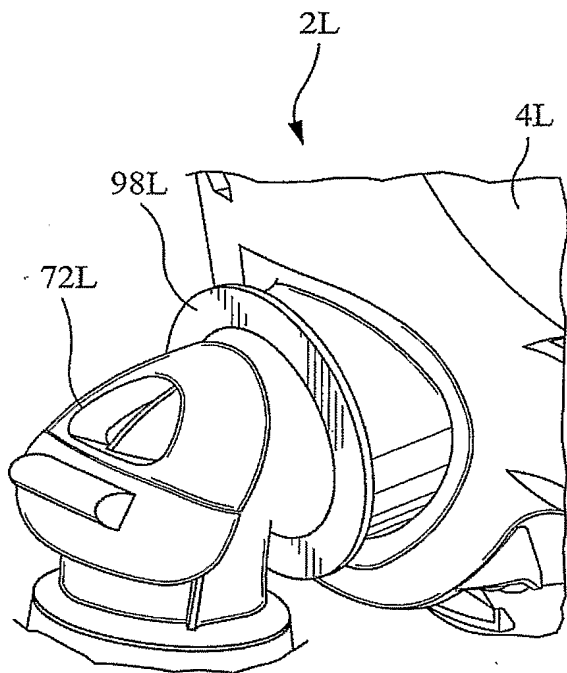


FIG. 23

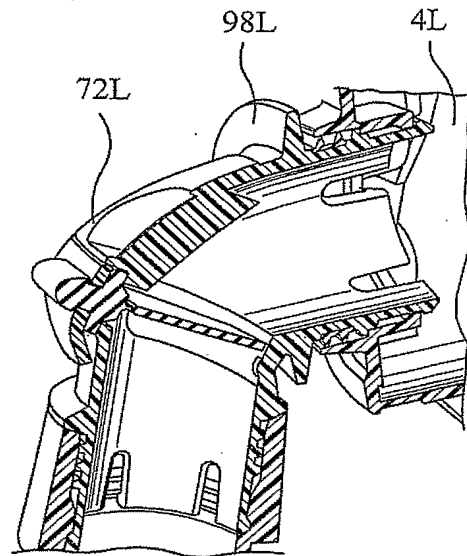


FIG. 24

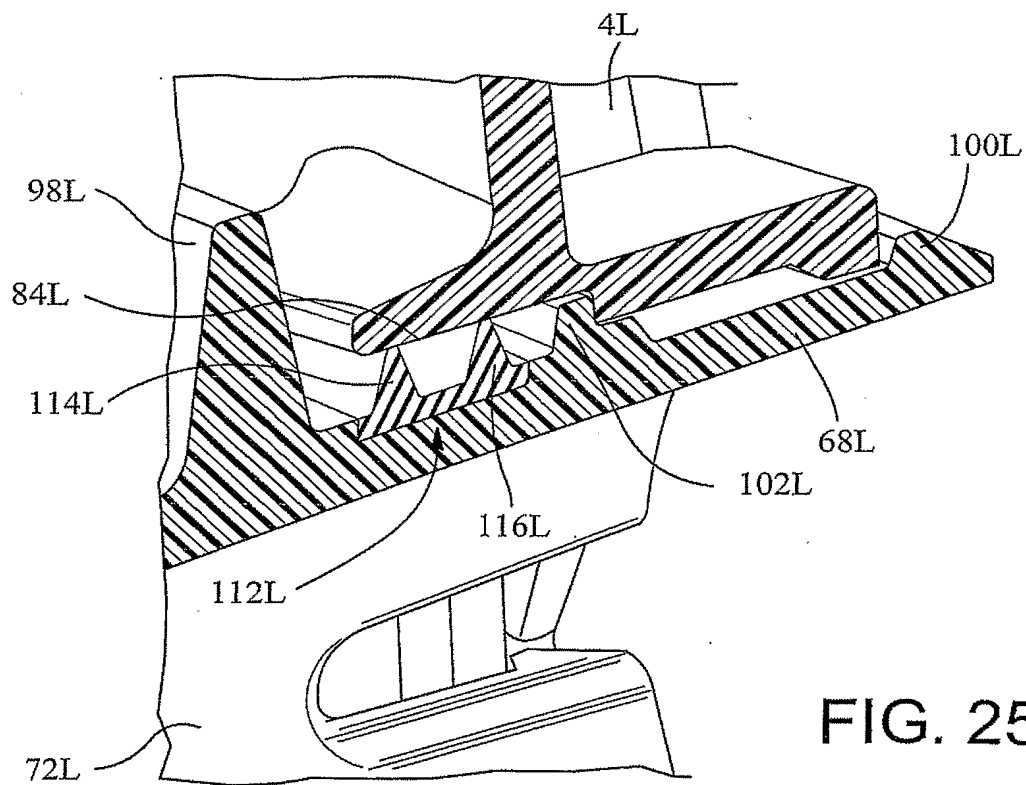


FIG. 25

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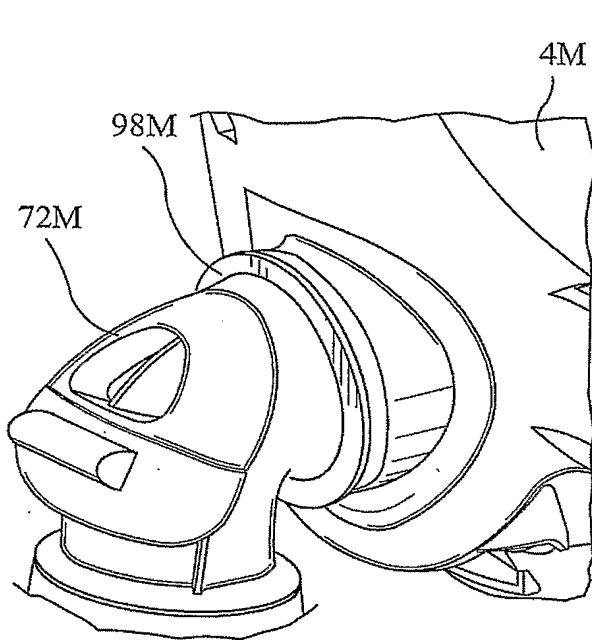


FIG. 26

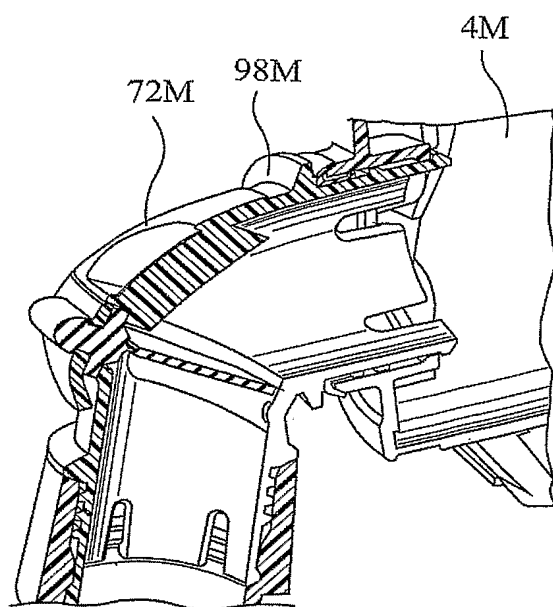


FIG. 27

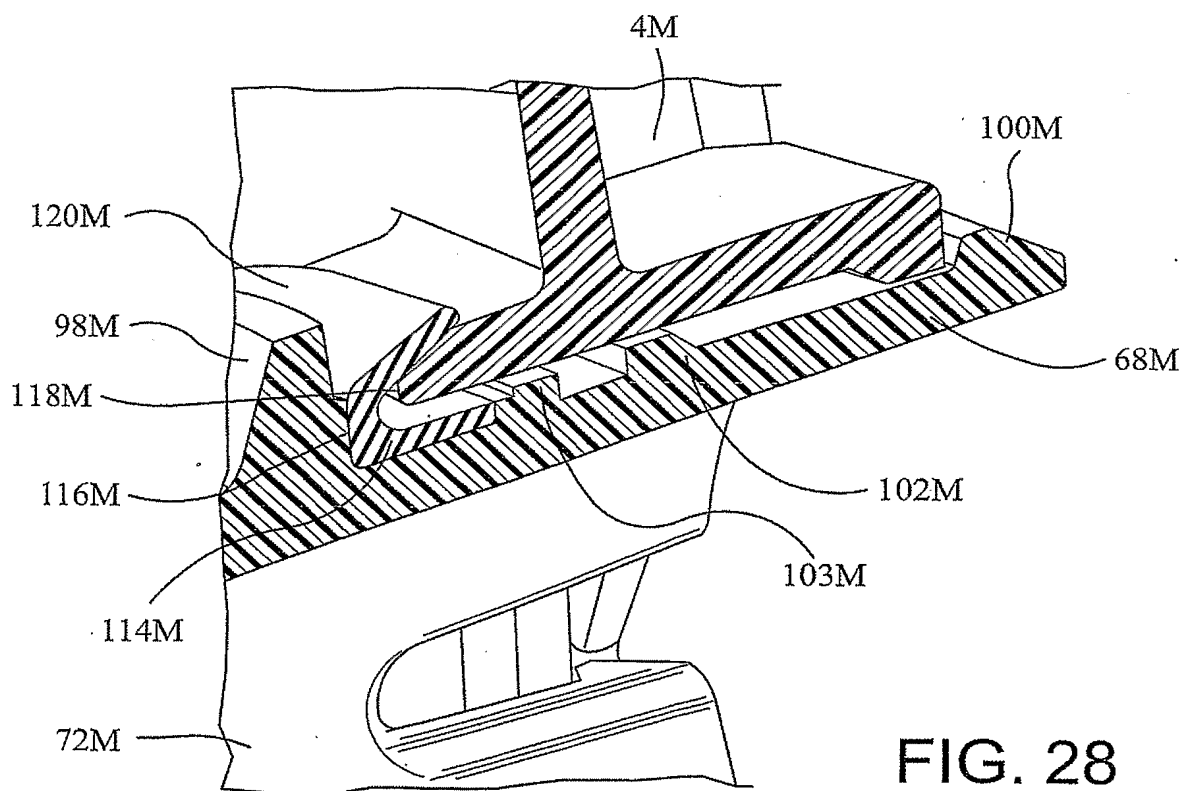


FIG. 28

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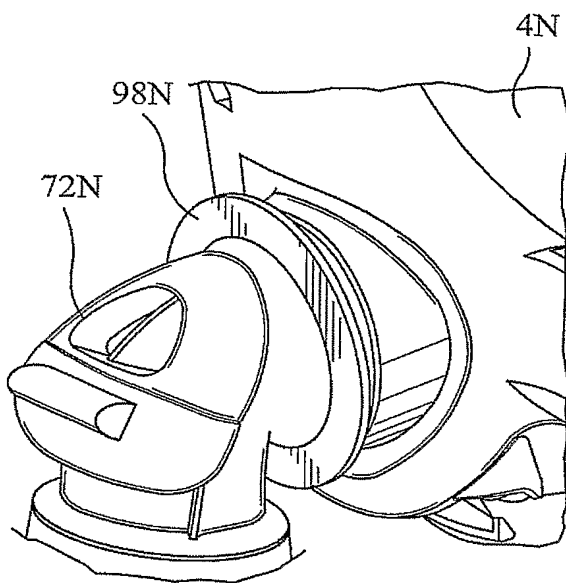


FIG. 29

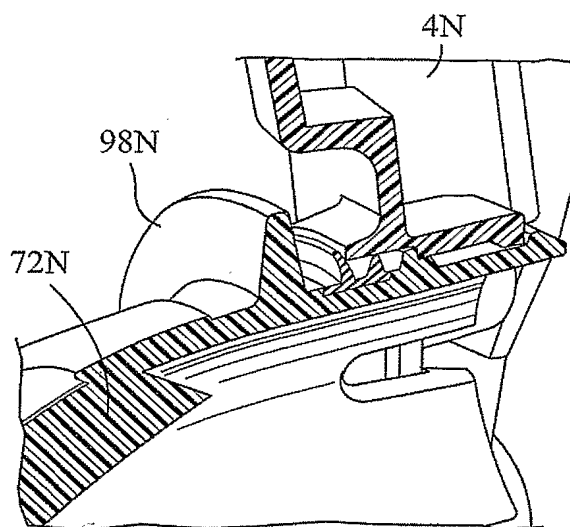


FIG. 30

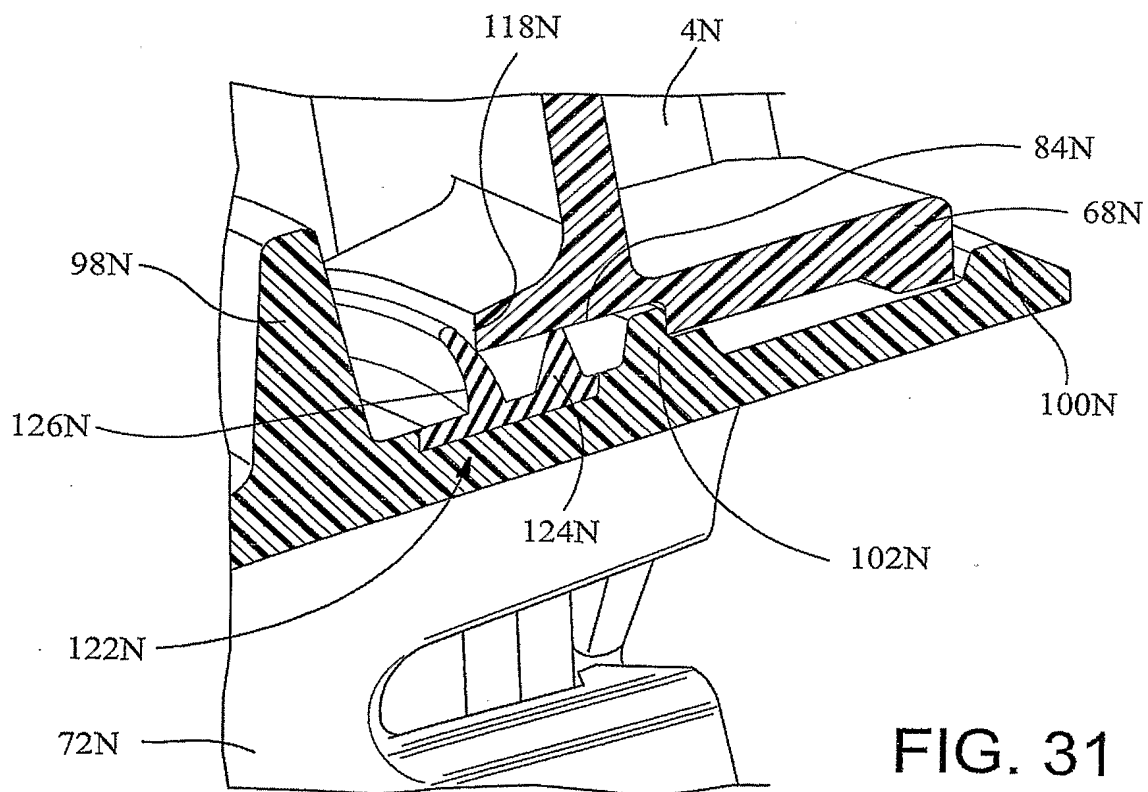


FIG. 31

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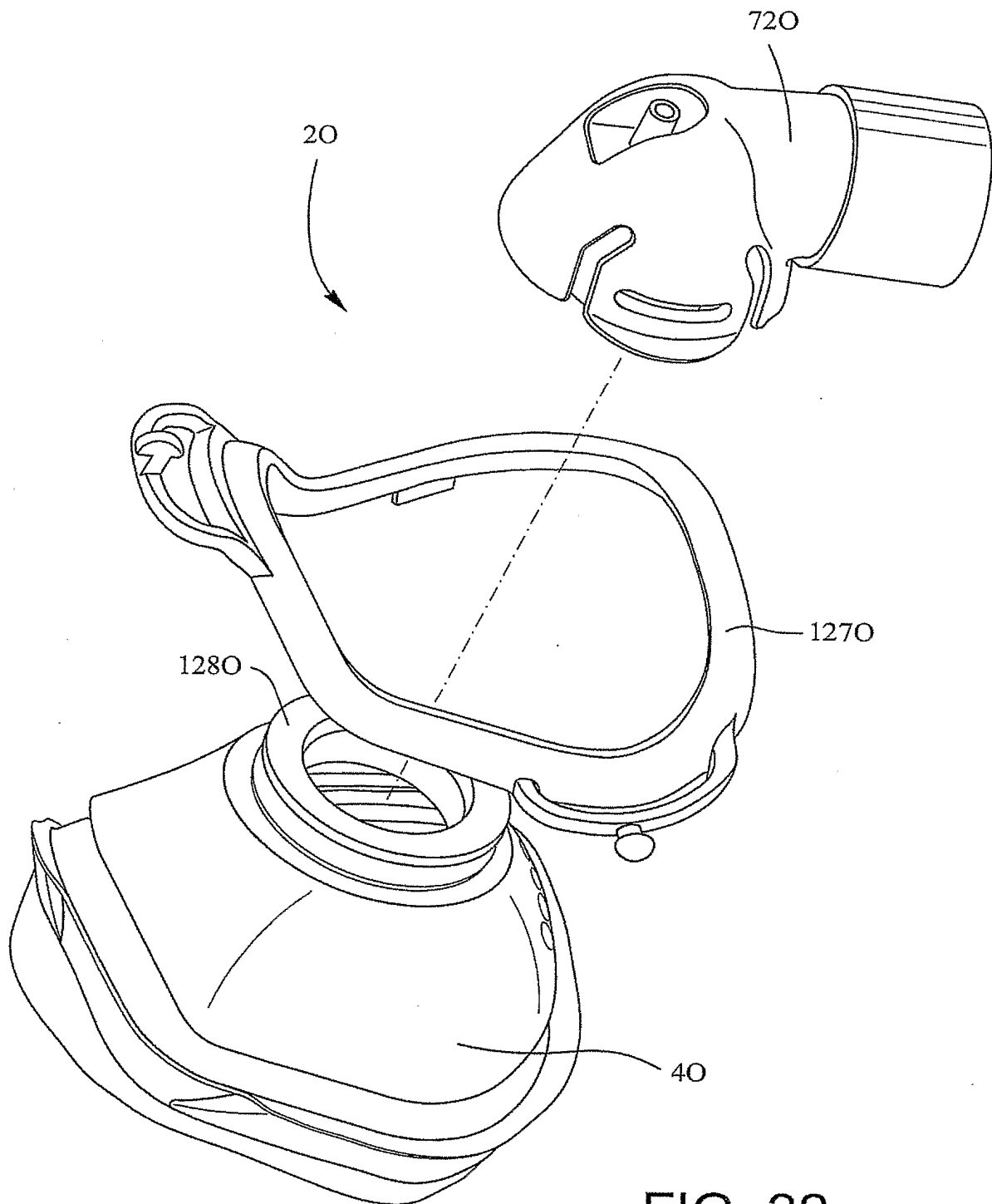


FIG. 32

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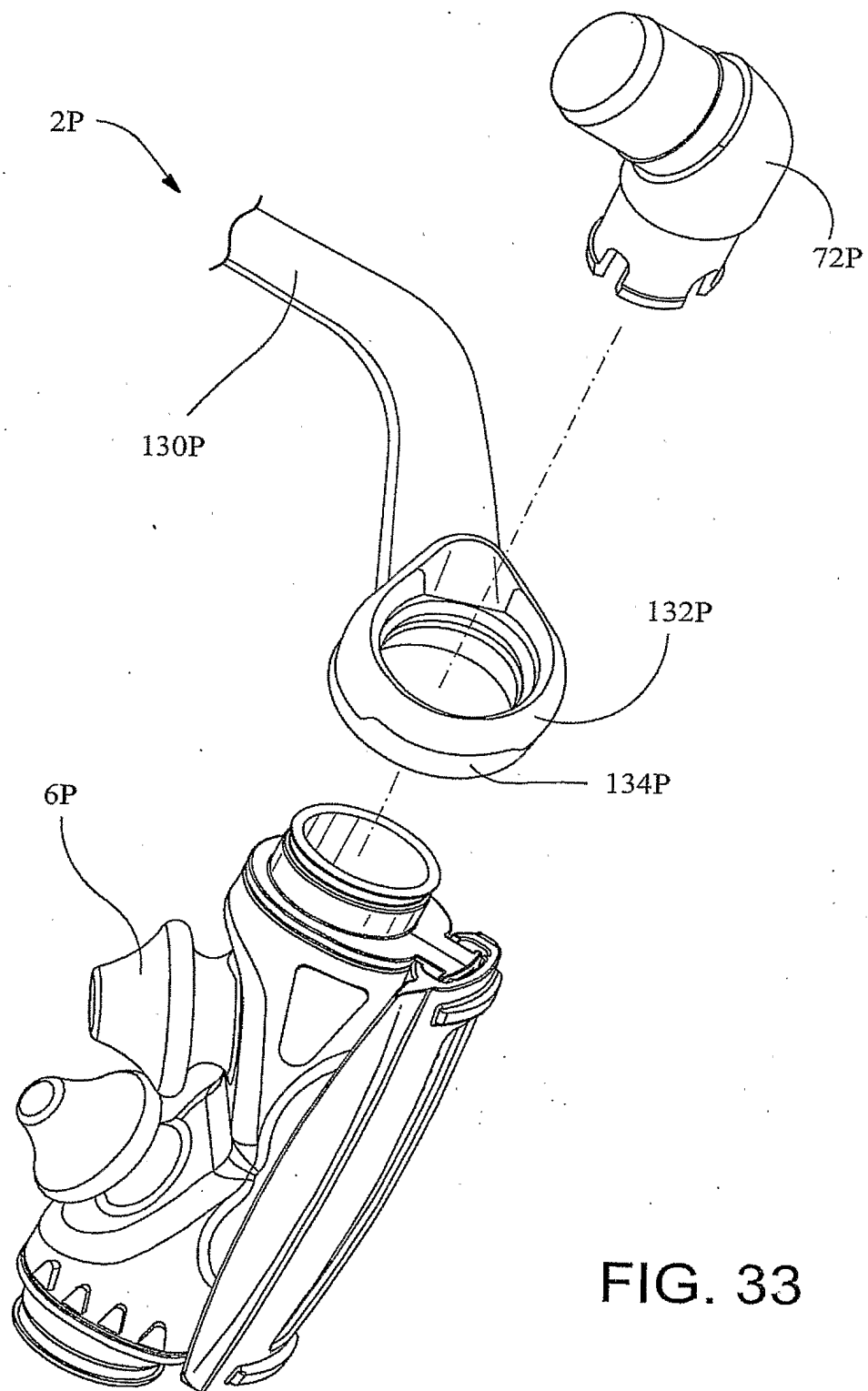


FIG. 33

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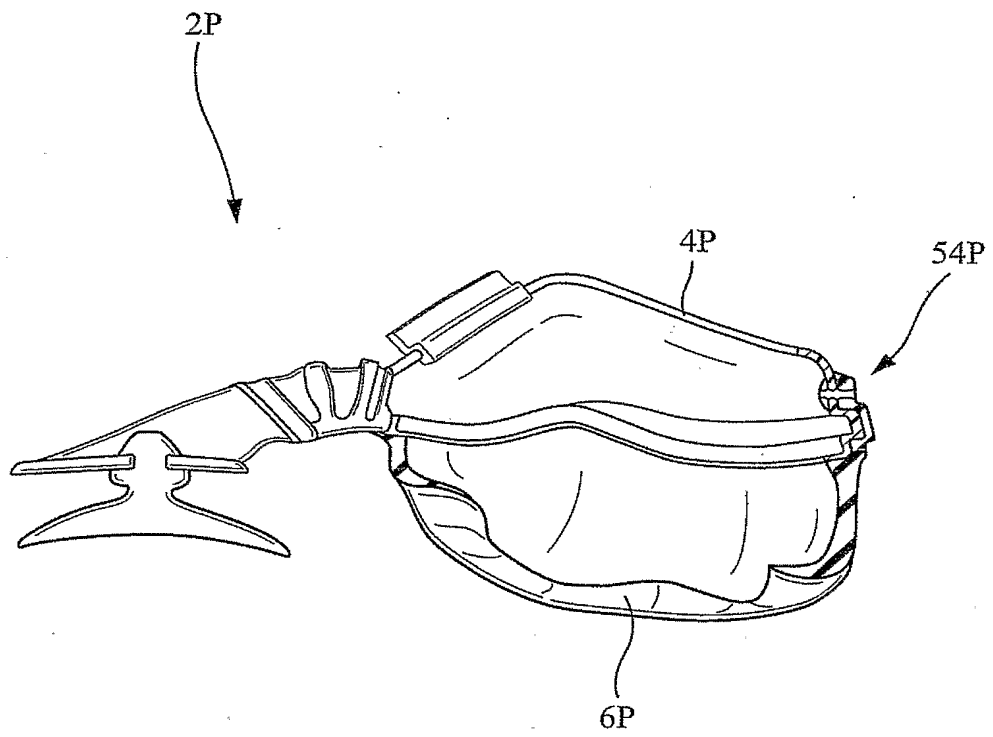


FIG. 34

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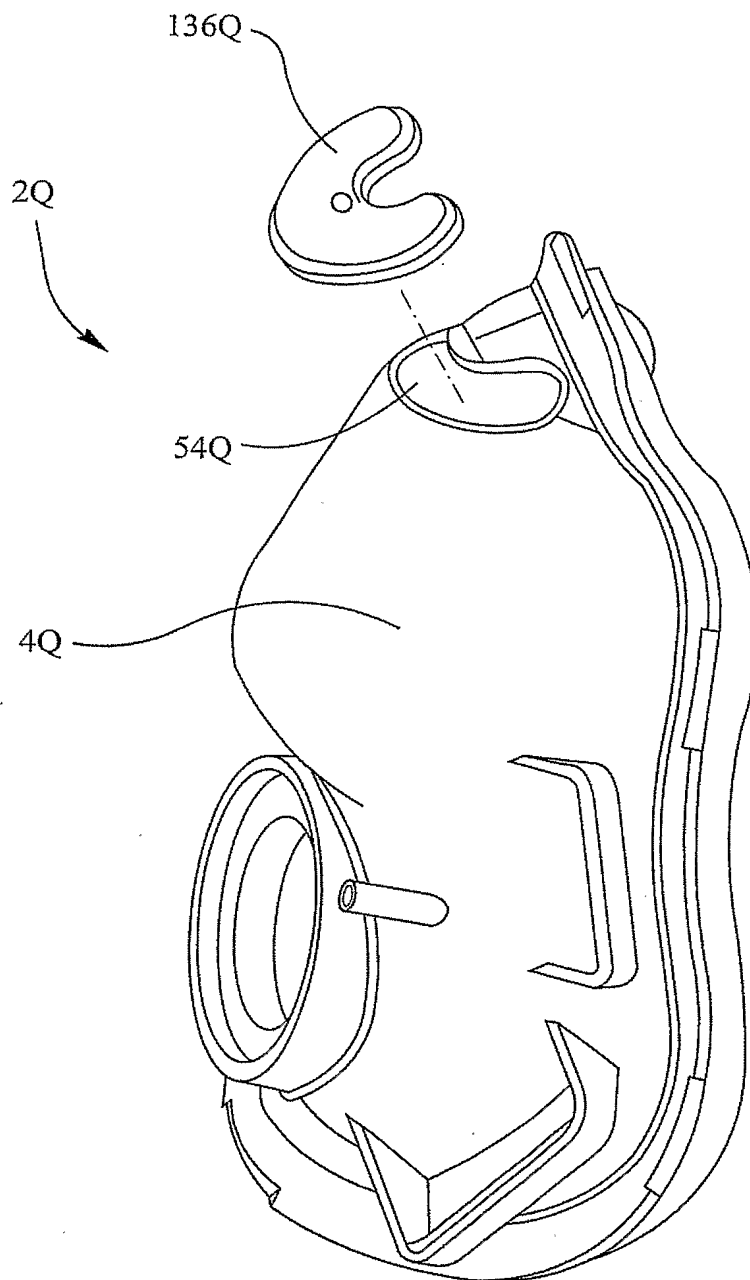


FIG. 35

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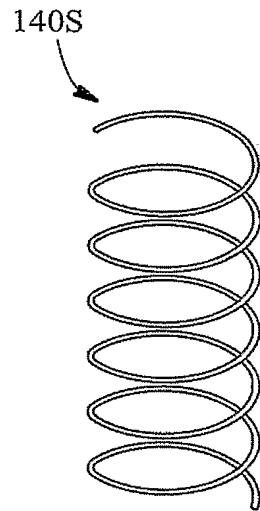


FIG. 36(a)

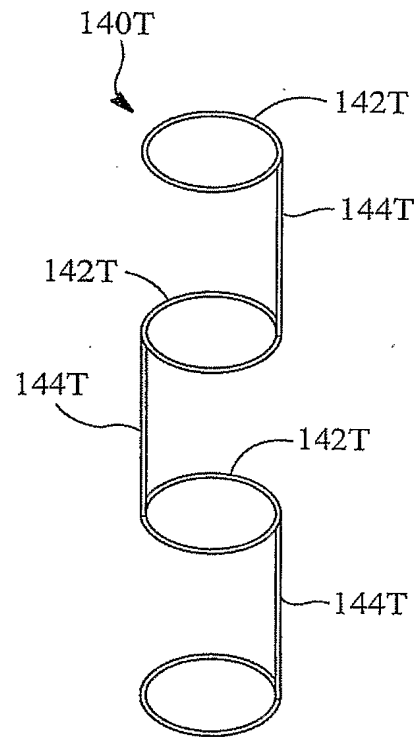


FIG. 36(b)

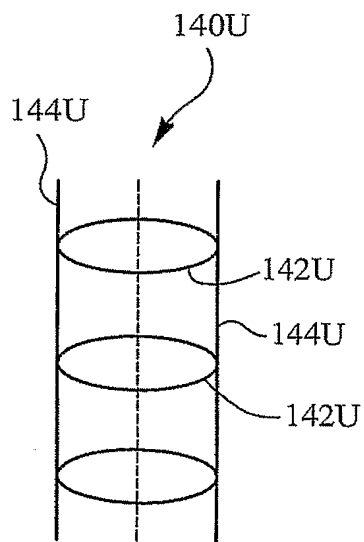


FIG. 36(c)

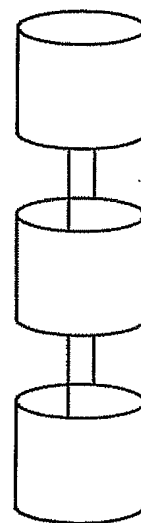


FIG. 36(d)

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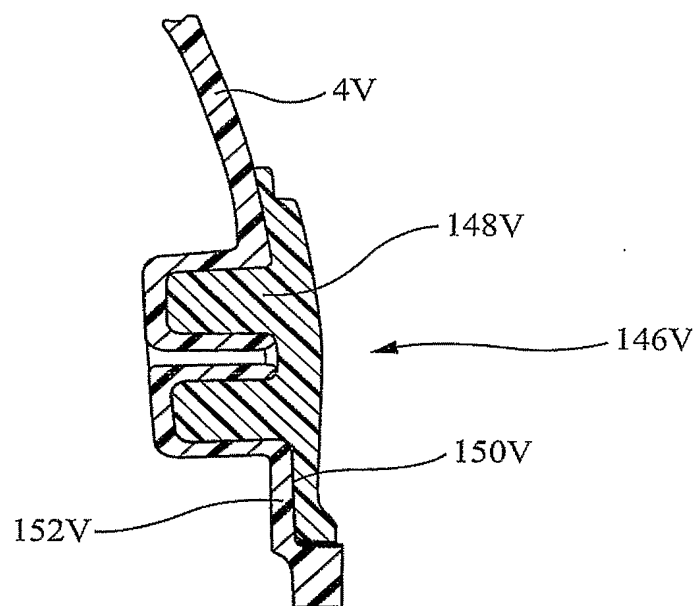


FIG. 37

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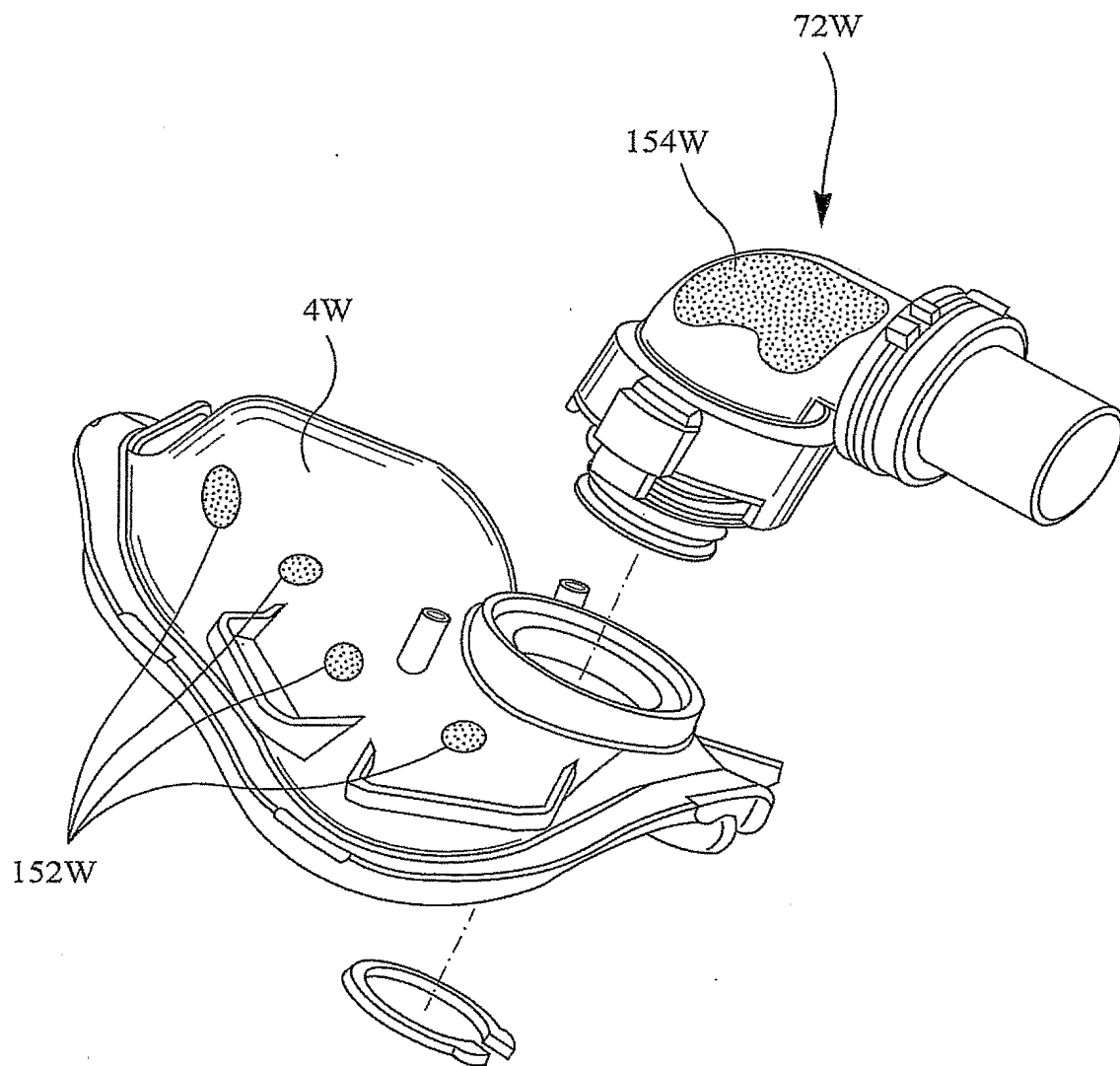


FIG. 38

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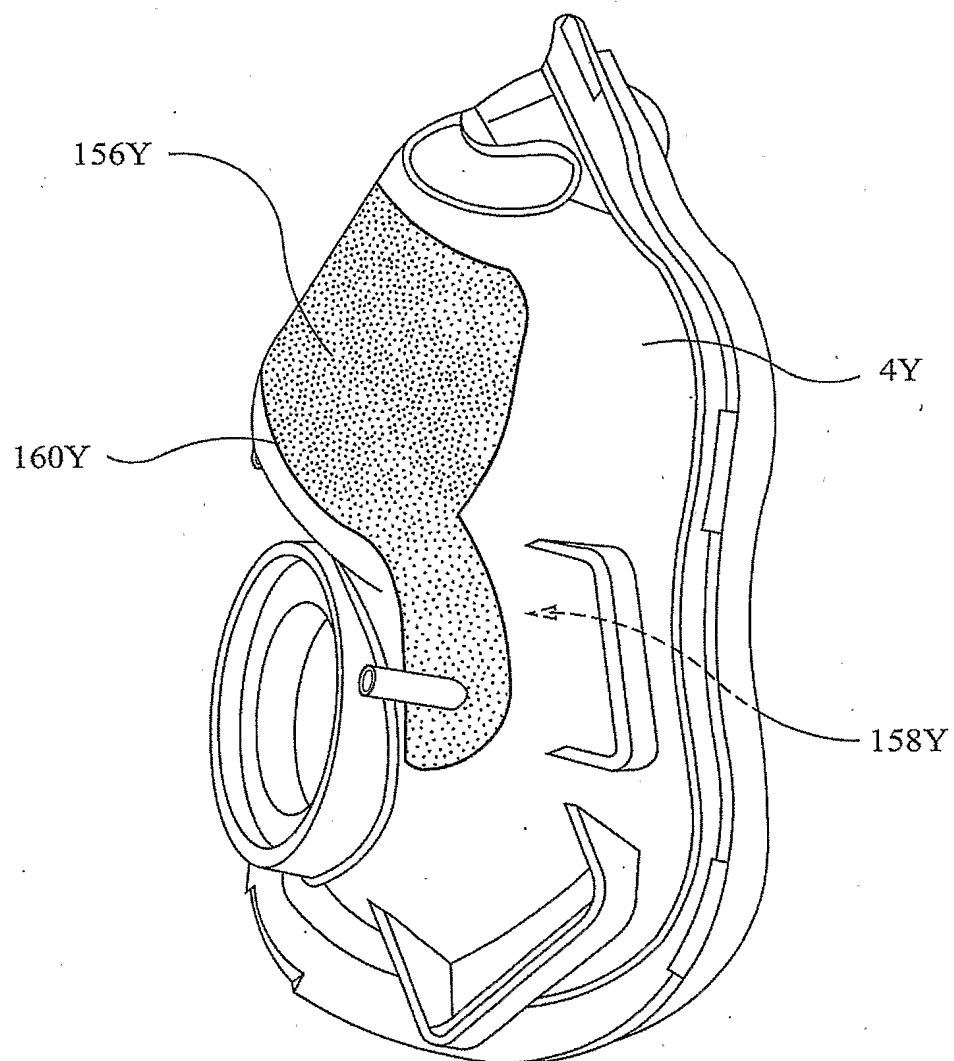


FIG. 39

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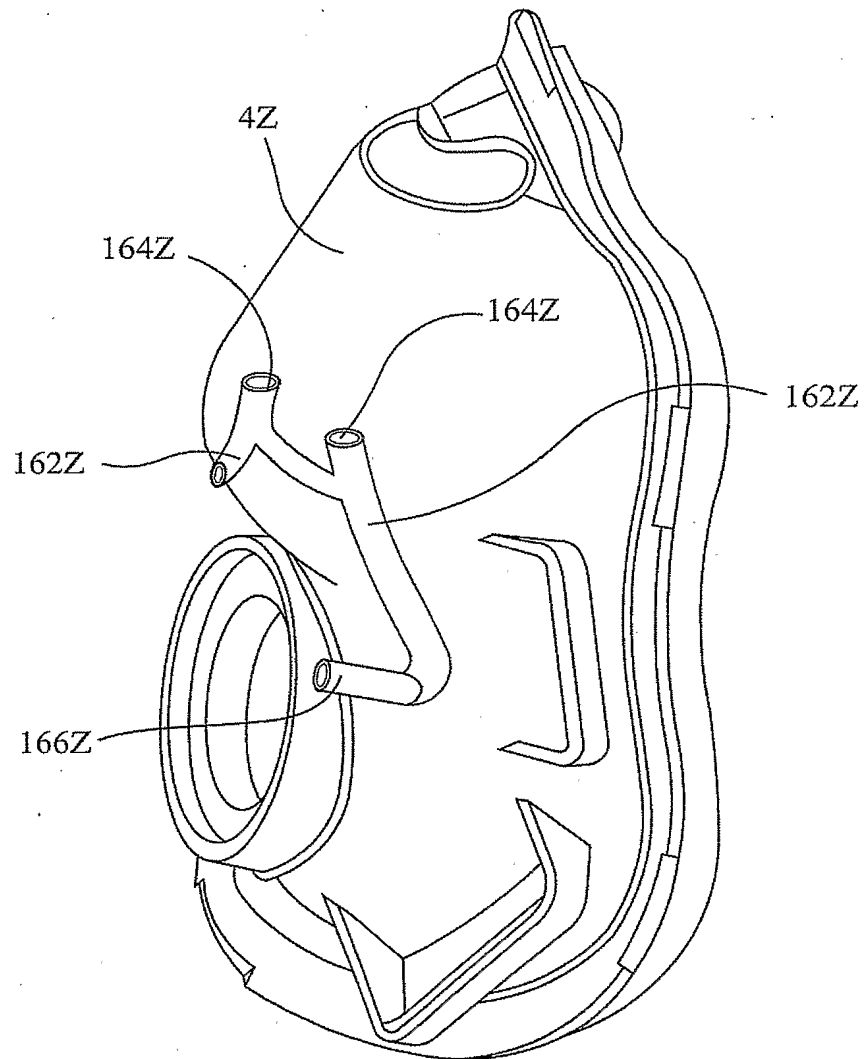


FIG. 40

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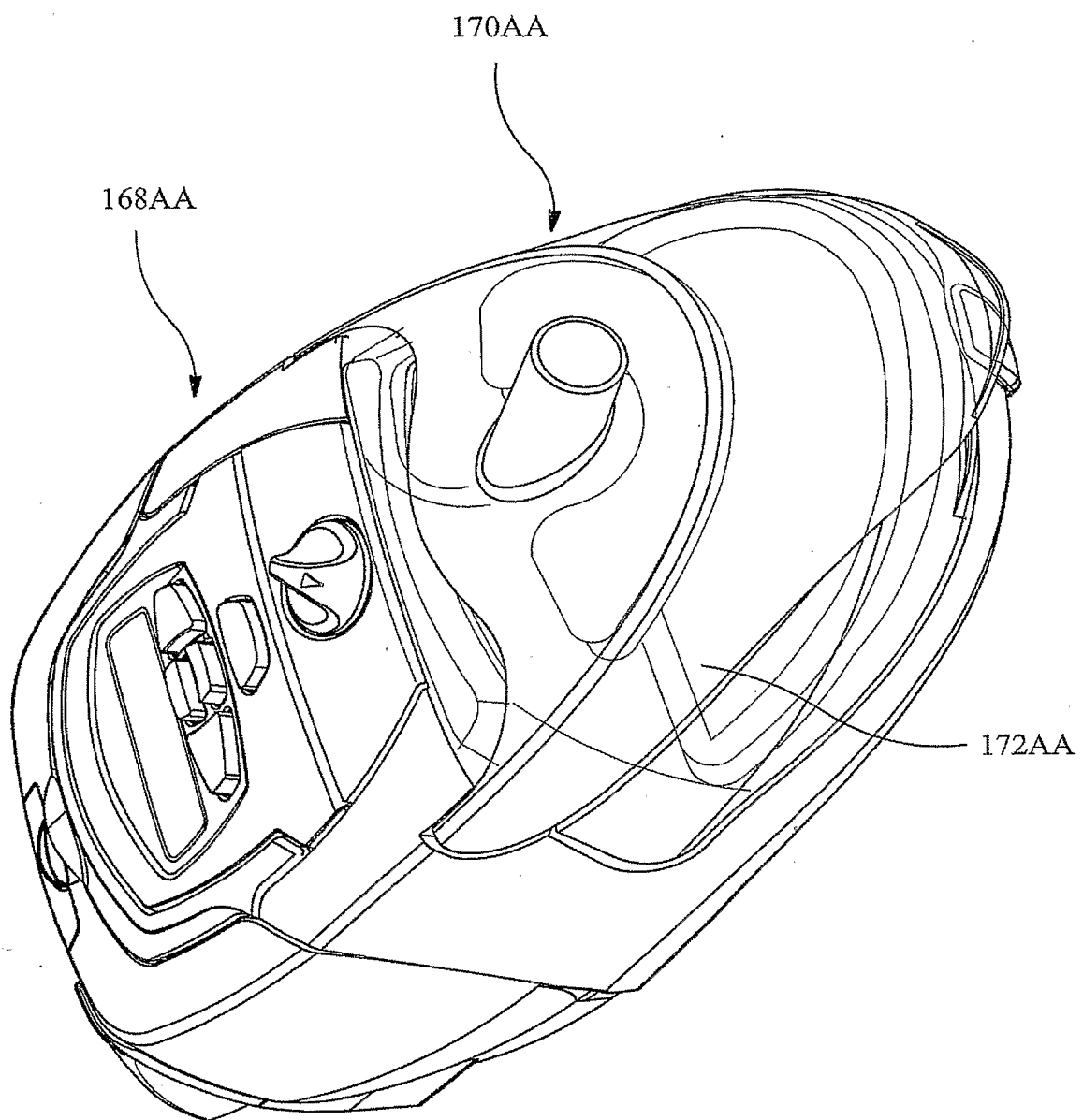


FIG. 41

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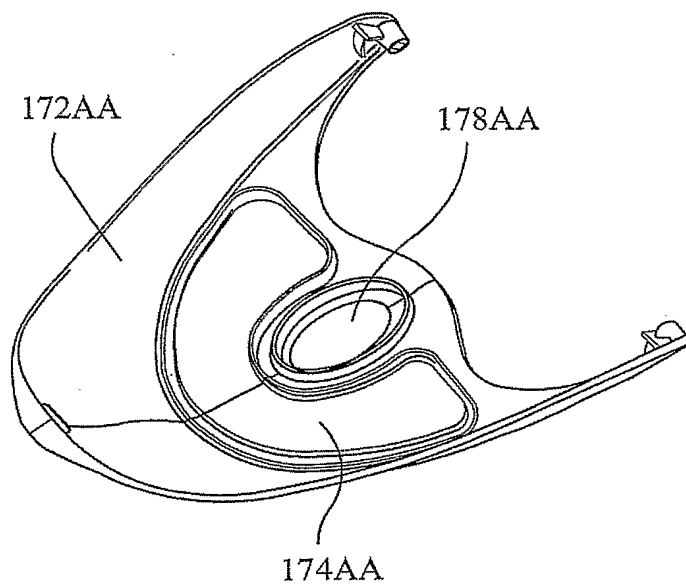


FIG. 42

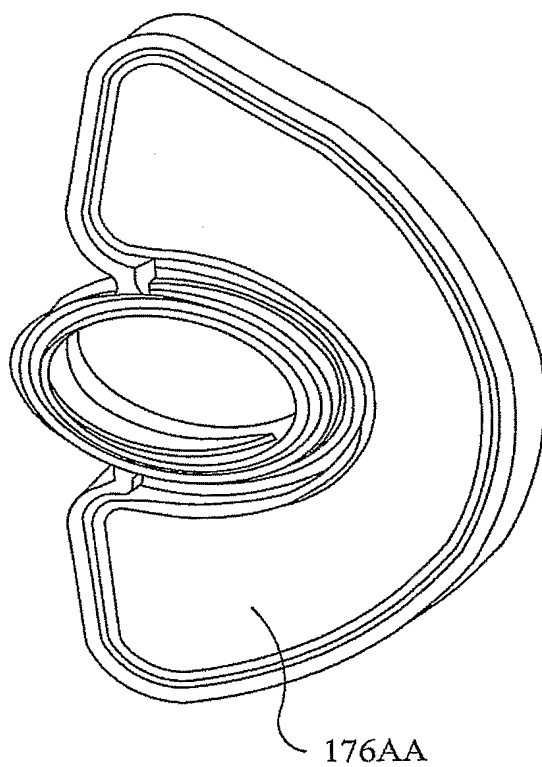


FIG. 43

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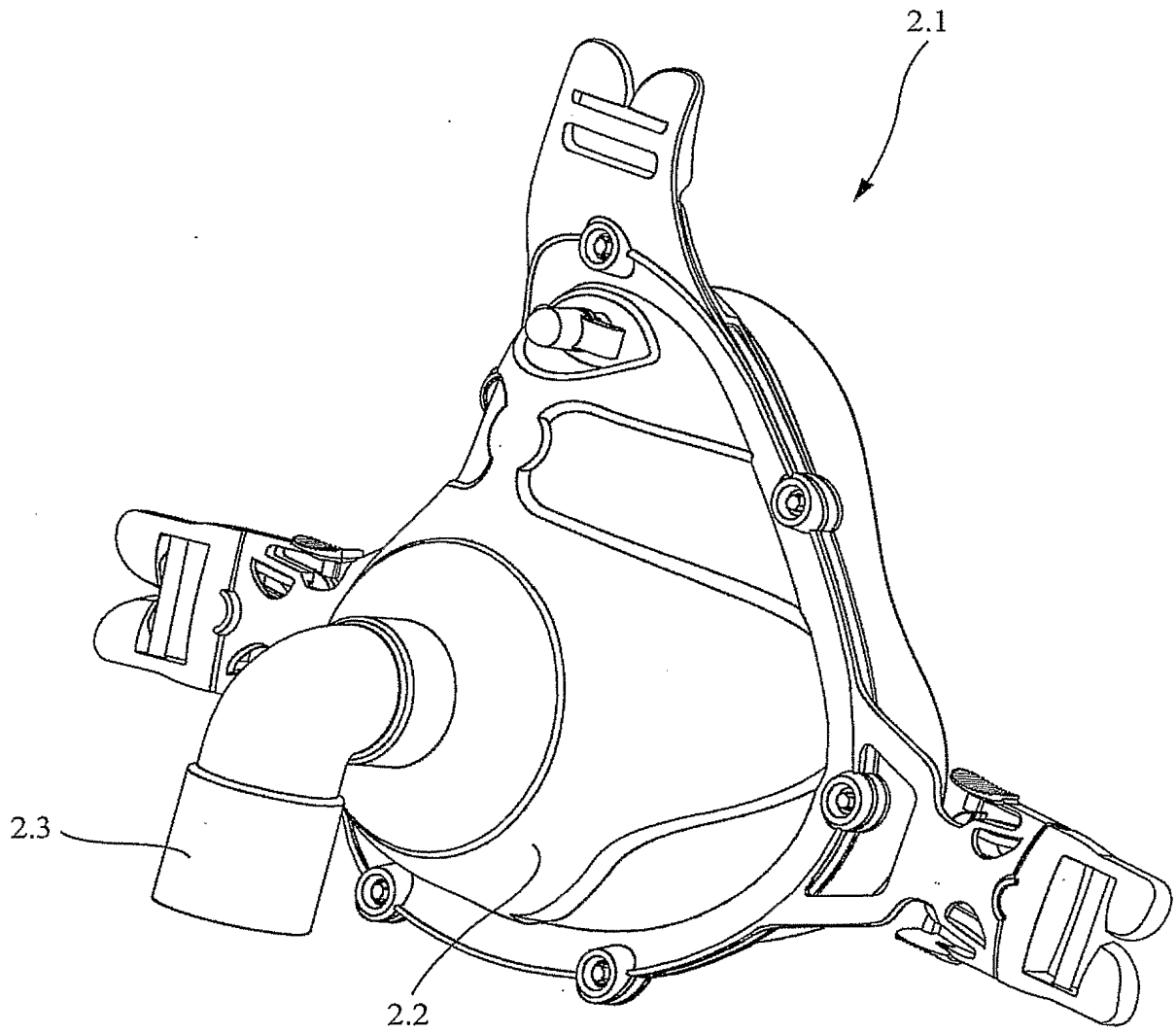


FIG. 44

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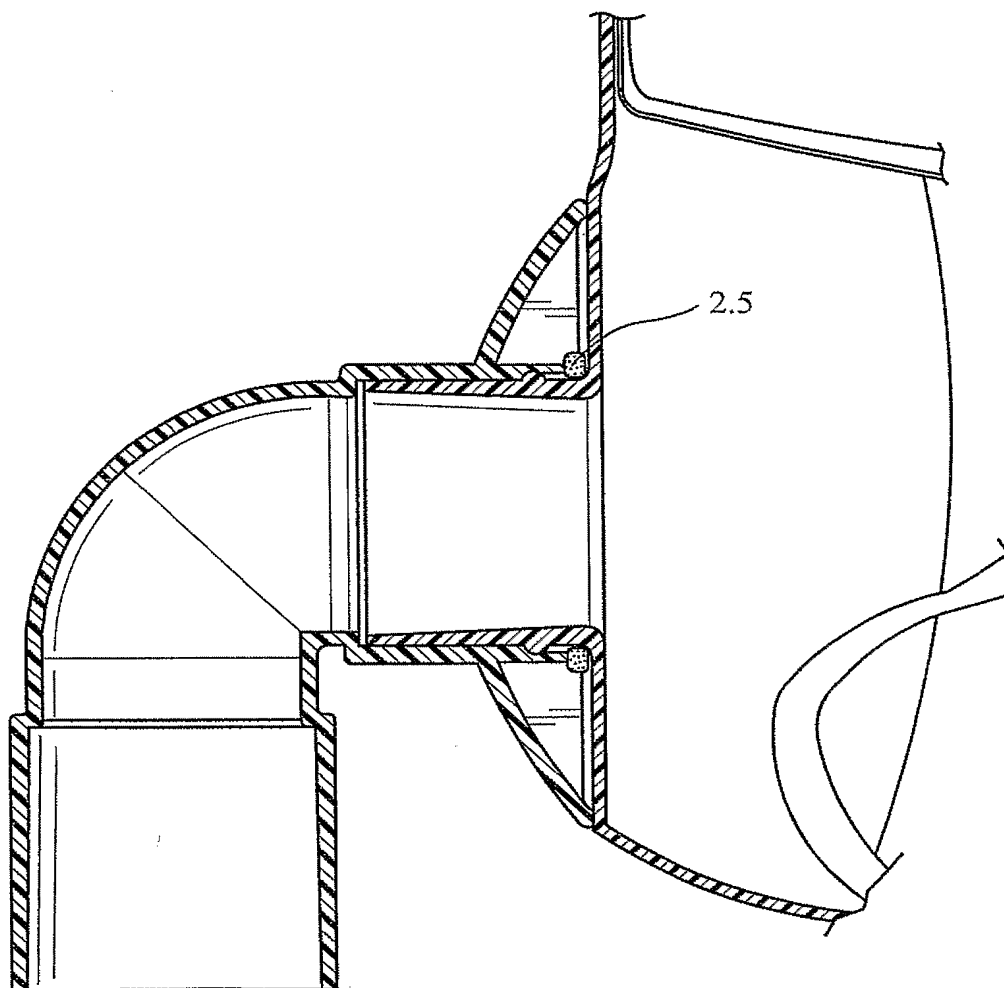


FIG. 45

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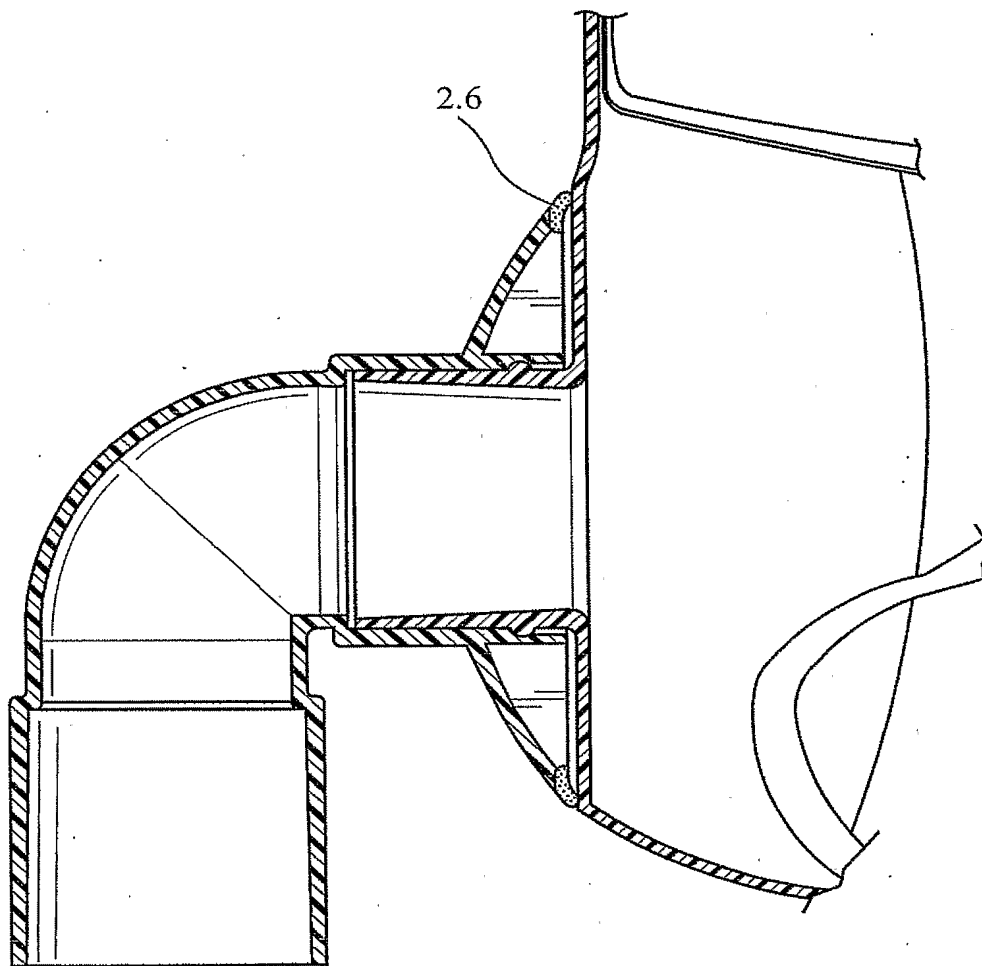


FIG. 46

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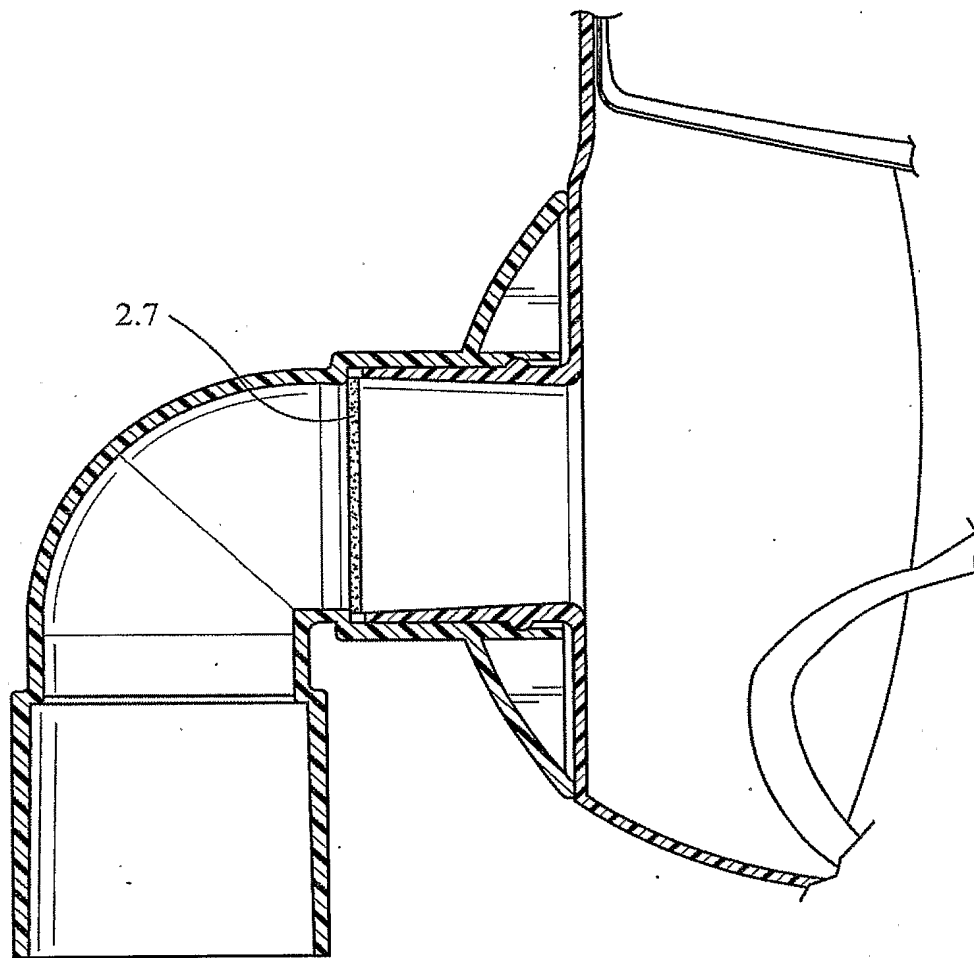


FIG. 47

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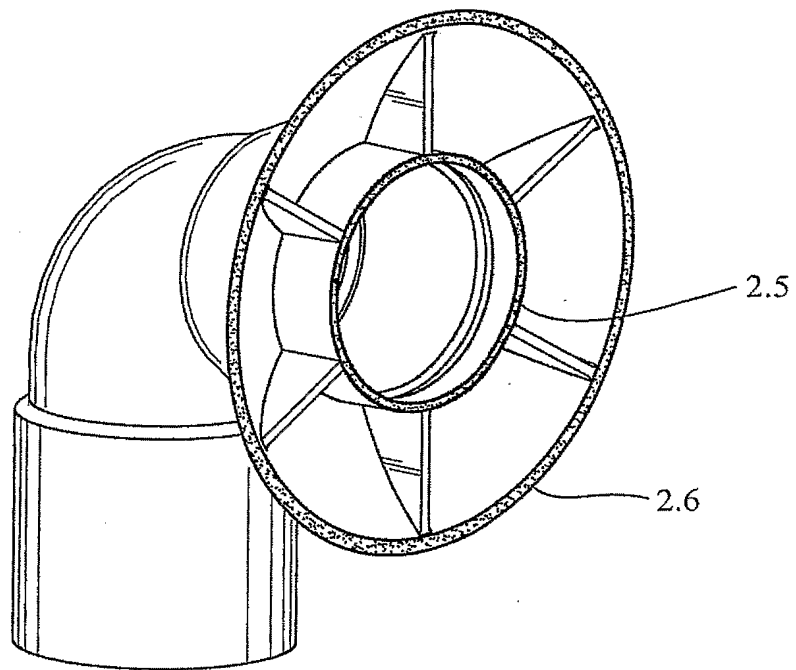


FIG. 48

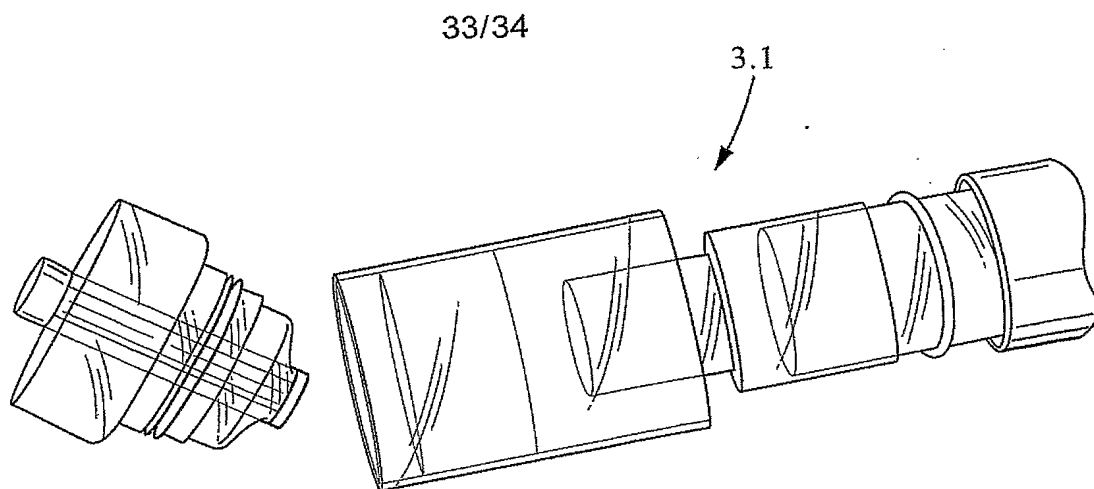


FIG. 49

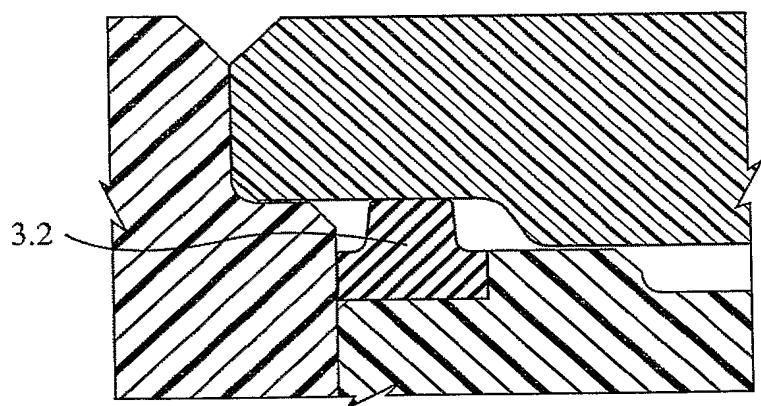


FIG. 50

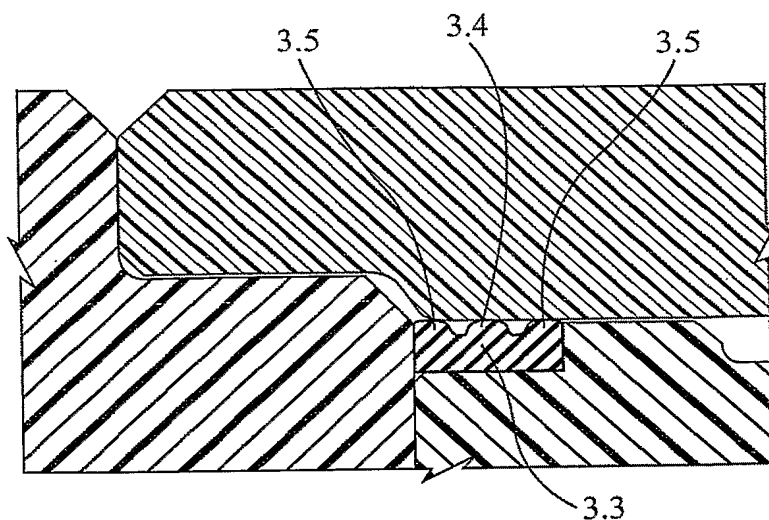


FIG. 51

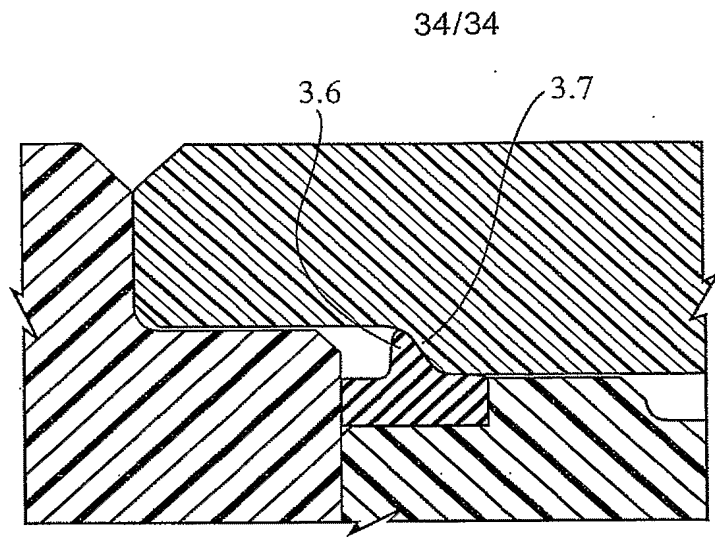


FIG. 52

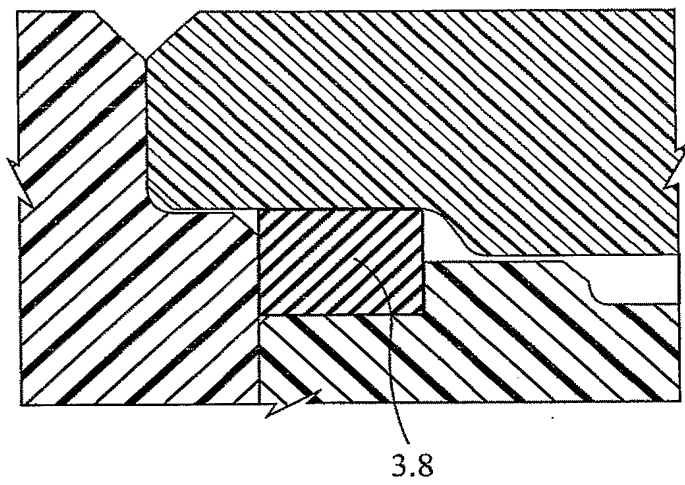
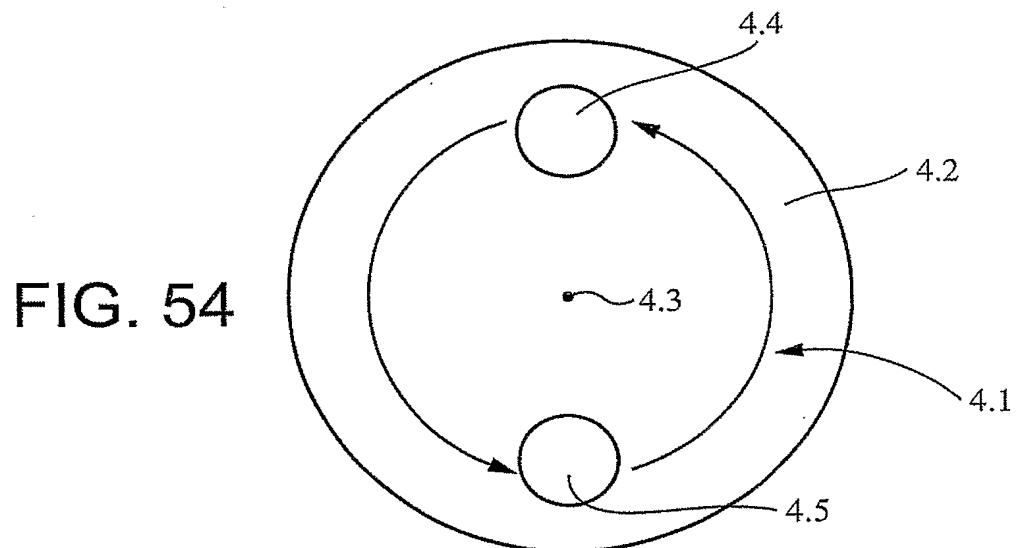


FIG. 53



INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001021

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. B29C 45/13 (2006.01) A61M 16/06 (2006.01) B29C 43/14 (2006.01) According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI: A61M B29C A62B mask interface patient respire breath treat abrade ablate plasma corona ion surface substrate base frame rigid hard stiff firm co over single combine integral mould mold form elastom silicon rubber lsr pliant flexible ESPACE: ECLA classes B29C 45/16H, 45/16L, 43/14, 45/13 with plasma mask, breath and similar terms USPTO: plasma treated surface silicone mould mold mask respiration breathing		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	GB 2038703 A (AIRCO LTD) 30 July 1980 Entire document and especially page 3 lines 38-41	1-25, 29-43 26-28
X	US 5391248 A (BRAIN) 21 February 1995 Column 5 line 53 to column 6 line 30, column 7 lines 40 to 48, figure 4	1-21
X Y Y	WO 2002/013884 A2 (NAMEY) 21 February 2002 Entire document and especially figures 4A, 4B	1-24, 29-34 26-28 35-94
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
*	Special categories of cited documents:	
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"
"E"	earlier application or patent but published on or after the international filing date	"X"
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 25 October 2006	Date of mailing of the international search report 30 OCT 2006	
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized officer MATTHEW FORWARD Telephone No : (02) 6283 2606	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/001021

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y Y	WO 2003/016018 A1 (INTERSURGICAL LIMITED) 27 February 2003 Pages 4 and 5 and figures	1-24, 29-34 26-28 35-94
X Y Y	GB 2397244 A (SMITHS GROUP PLC) 21 July 2004 Page 4	1-24, 29-34 26-28 35-94
Y Y	US 4317788 A (IMADA et al) 2 March 1982 Abstract	26-28 35-94
Y Y	US 4344981 A (IMADA et al) 17 August 1982 Abstract	26-28 35-94
Y Y	US 6773776 B2 (GUST) 10 August 2004 Entire document	26-28 35-94
Y Y	US 6902812 B2 (VALINT et al) 7 June 2005 Entire document	26-28 35-94
A	US 6409954 B1 (MULLIGAN) 25 June 2002 Figures	1-94

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/001021

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See Supplemental Box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: **1 to 94**
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1 to 34 are characterised by the manufacture of a respiratory mask having a first component of an elastomeric material and a second component of a less flexible material than the first. The first component is "integrally formed onto the second". It is considered that moulding an elastomeric material onto a less flexible material to manufacture a face mask comprises a first distinguishing feature. Claims 22 to 29 are considered to particularly define this concept.
- Claims 35 to 94 are characterised by a mask having a relatively rigid substrate with a portion treated to receive a "reactive substance" and an elastomer that is more flexible than the substrate and secured to the substrate via an "induced adhesive bond" between the treated portion and the elastomer. Claim 147 defines a similar arrangement for a humidifier tub for a flow generator. It is considered that securing a flexible portion of a mask to a rigid portion via an induced adhesive bond at a treated portion of the rigid portion comprises a second distinguishing feature. Claims 82 to 89 when appended to claim 35 are considered to particularly define this aspect.
- Claims 95 to 146, 148 and 149 define a method of manufacturing a respiratory mask having a rigid substrate and over moulding an elastomer "to or with" the substrate onto a selected portion of the substrate. It is considered over moulding an elastomer onto a selected portion of a rigid mask substrate comprises a third special technical feature. Claims 116 to 117, 118, 119, 120, 121, 122 to 125, 126, 127, 128, 129, 130, 131, 132 to 133 and 134 are all considered to define a similar concept. Each of the independent claims defines various particular forms of the rigid substrate and the elastomer. Claims 135 to 146 are appended to the earlier claims. Claims 148 and 149 are considered to define this same concept applied to humidifier tubs. In this claim set, claim 135 when appended to claim 95 are considered to particularly define the concept.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2006/001021

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
GB	2038703	AU	53113/79	CA	1133214
		FR	2443918	ZA	7906399
US	5391248	AU	39582/93	AU	45803/93
		CA	2100998	CA	2107027
		EP	0651664	MX	9301163
		US	5241956	US	5305743
		WO	9402191	WO	9417848
WO	0213884	AU	84804/01	CA	2417168
		US	2002020416	US	2004149287
WO	03016018	GB	2367525		
GB	2397244	US	2005098183		
US	4317788	DE	3022547	FR	2459261
		JP	56000830	GB	2051827
US	4344981	DE	3022546	GB	2051844
US	6773776	BR	9806345	DE	19834065
US	6902812	AU	50229/00	BR	0011604
		CN	1351630	EP	1187873
		MX	PA01011854	US	6630243
		US	2003224185	WO	0071613
US	6409954			CA	2373561
				HK	1044554
				US	2002102415
				ZA	200109522
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
END OF ANNEX					